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TRANSFORMATION OF THE MEDICAID PROGRAM—Part 1

Y 4. C 73/8: 104-106

Transformation of the Medicaid Prog...

HEARINGS

BEFORE THE

SUBCOMMITTEE ON
HEALTH AND ENVIRONMENT

OF THE

COMMITTEE ON COMMERCE
HOUSE OF REPRESENTATIVES

ONE HUNDRED FOURTH CONGRESS

FIRST SESSION

JUNE 8 AND 15, 1995

Serial No. 104–106

Printed for the use of the Committee on Commerce

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TRANSFORMATION OF THE MEDICAID PROGRAM

THURSDAY, JUNE 8, 1995

HOUSE OF REPRESENTATIVES,
COMMITTEE ON COMMERCE,
SUBCOMMITTEE ON HEALTH AND ENVIRONMENT,
Washington, DC.

The subcommittee met, pursuant to notice, at 9:34 a.m., in room 2322, Rayburn House Office Building, Hon. Michael Bilirakis (chairman) presiding.

Members present: Representatives Bilirakis, Hastert, Barton, Upton, Stearns, Klug, Franks, Greenwood, Burr, Bilbray, Whitfield, Ganske, Norwood, Coburn, Bliley (ex officio), Waxman, Brown, Lincoln, Deutsch, Stupak, Wyden, Hall, Towns, Pallone, and Dingell (ex officio).

Staff present: Howard Cohen, majority counsel; Melody Harned, majority counsel; Mary McGrane, majority counsel; Bridgett Taylor, minority professional staff member; and Chris Knauer, minority investigator.

Mr. BILIRAKIS. The hearing will come to order.

Before the Chair goes into his opening statement, I would like to announce that in the interests of time because we know that our distinguished guests don't have really that much time with us, I am going to limit opening statements to myself, to Mr. Waxman, Messrs. Bliley and Dingell. I ask the remaining members please to submit your statement for the record.

And I also would afford the Governors a 10-minute period of time in terms of your statements, although our questioning would be limited to 5 minutes.

Today begins a series of hearings that this subcommittee will have on the Medicaid program. It is a special pleasure for me to welcome this group of distinguished Governors to testify on the state of the Medicaid program and their ideas about restructuring the program. As we all know, many of the Medicaid mandates first originated in this subcommittee. You, our Nation's Governors, then had to finance these expansions, and administer a program which began to devour, you have told us this over the years, your State budgets.

In the past years, following the Medicaid program has been like riding a roller coaster. Beginning in 1987, we have a string of Medicaid expansions, the prototype for Federal unfunded mandates. They were all written into complicated reconciliation bills in the middle of the night. No hearings, no study, no consultation with

the Governors, no consideration of the impact on Federal and State budgets.

They came in a tidal wave as part of bills like the Omnibus Reconciliation Act of 1987, which we fondly call OBRA–87, the Tax Technicals of 1988, the Family Support Act, the Medicare Catastrophic Coverage Act, OBRA 1989 and OBRA 1990. And they have proved the old adage, that haste sometimes makes waste.

The cumulative impact of what Mr. Bliley has termed "midnight Medicaid mandates" has been staggering, not just for the Federal budget but for the Governors and State taxpayers as well. Medicaid spending has been exploding, growing at an average annual rate of 19 percent between 1990 and 1994. We know that in virtually every State it is the fastest growing part of their budgets.

Certainly, the Governors and the National Governors' Association has been attempting to redress this problem for years. In August 1989, 49 Governors, including then-Governor Clinton of Arkansas, signed a resolution asking Congress for a 2-year freeze on the enactment of further Medicaid mandates. They stated, "Our resolution was based on our increasing concern with the impact of the last 3 years of Medicaid mandates on our budgets, and consequently, on our ability to properly fund education and other important services." Unfortunately, Congress under its old leadership responded to this honest request by then passing eight new unfunded Medicaid mandates in reconciliation bills in 1989 and 1990. So much for the voice of Governors in those years.

This was followed by a second National Governors' Association resolution unanimously approved by all Governors, including then-Governor Clinton who was on the task force who drafted the resolution, requesting modifications and delays in all of these mandates.

This resolution stated, "Currently, 31 States are struggling with budget shortfalls. A significant part of the fiscal pressure on States is coming from increased costs in the Medicaid program. The increased costs of Medicaid not only represent the generally inflated costs of health care but are exacerbated by 4 years of Medicaid mandates." Let me finish by making some brief comments concerning the extensive micromanagement of this program by the Health Care Financing Administration, HCFA.

For too long, the States have been under the yoke of arcane HCFA regulations, rules, manual instructions, and transmittals. You have been buried under an avalanche of Washington bureaucrats and needless paper. Even when a State attempts to create an innovative program, this is what happens.

And I see that my Governor from Florida, Governor Chiles, is not here, but I think he would appreciate this. This Governors ladies and gentlemen, Governor Chiles, is a copy of the State of Florida's official 1115 waiver application. I might add this is printed on both sides of the sheets, which does not include the thousands of pages of additional backup documentation. This represents the obstacle course, you have gone through it, many of you, that HCFA places in front of States in their attempt to create innovative delivery systems tailored to the needs of their citizens. We need to make this model of top-down HCFA micromanagement and restructure this

program so that States can have the flexibility to create health programs for the 1990's.

Thank you. At this time I would recognize Mr. Waxman for his opening statement.

Mr. WAXMAN. Thank you very much, Mr. Chairman.

This is the first of the historic series of hearings. This committee has been instructed by the Republican Majority to report out legislation by July 14th that cuts Federal Medicaid spending by a staggering $187 billion over the next 7 years.

It is hard to overstate the severity of this cut, as you can see from chart one. Under the Republican cuts, in the year 2002, the growth in Federal Medicaid spending would be slashed from 9.3 percent to 1.9 percent. As a result, Federal payments to the States will drop from projected levels by nearly $57 billion, or 32 percent, in that year alone.

Perhaps in order to mask the effects of these massive cuts, the Republican Budget Committee report stipulates that the remaining Federal Medicaid spending be distributed to the States in the form of a block grant. Under a block grant, over 30 million Americans, more than half of whom are children, would lose their guarantee of health insurance coverage and join the ranks of the uninsured. Over 10 million elderly and disabled Americans would lose their coverage for nursing home and other long-term care.

The Republican Budget Committee's purpose in block granting Medicaid is clear: They want to limit the Federal Government's financial responsibility for health care and for long-term care. They also want a place in the Federal budget to go to in the future to get large savings for additional deficit reduction or additional tax cuts.

Anyone with any doubt about the fiscal destiny of the Republican Medicaid block grant need only look at the Budget Committee's recommendations with respect to the maternal and child health block grant and the preventive health block grant. These two block grants, first established at the request of the Reagan administration in 1981, are cut by more than three-fifths next year in this Republican budget.

Today's hearing will focus on problems in the current Medicaid program. We can all agree that the Medicaid program has many problems and can be improved. But the real issue before this committee is not whether the current program has problems or what those problems are. The real issue is how in the world are the States going to be able to handle the loss of $187 billion in Federal Medicaid funds over the next 7 years and what this will mean for the people who are relying on this program.

Unfortunately, we have no legislative proposal before us, even though we have only 5 weeks until we have to report out our recommendations. When we do I hope that the chairman will reserve at least as much hearing time for his proposal as he has allocated to an examination of the current program.

There are issues which we can start discussing today even in the absence of legislative language. We don't need legislative language to estimate the effect of the proposed cuts in coverage.

The Kaiser Commission's independent analysis of the Medicaid cuts in the House Republican budget contains a summarized in

chart, No. 3. Under the Republican cuts, even if States hold the growth in spending for beneficiaries to the rate of inflation, nearly 4 million Americans will lose Medicaid coverage in the year 2002 alone.

In the States represented here this morning, by Governors who are testifying, the numbers of Americans losing coverage would range from over 30,000 in Utah to over 115,000 in Tennessee, and in Florida, the chairman's home State, the number of residents losing coverage would be over 430,000.

Of course there is no way to know who those 4 million Americans will be. That is the whole point of the block grant. It is a mechanism that leaves the States with the burden of deciding whether to terminate coverage for the elderly or the disabled or mothers and children, or all of the above.

Regardless of how efficient they are, unless they replace the lost Federal Medicaid dollars with their own funds, they will have no choice but to cut back on coverage.

The Kaiser Commission's analysis assumes States will continue to spend their own funds in order to draw down Federal Medicaid matching funds.

Of course there is much opposition to that requirement among proponents of block grants. If States are no longer required to spend their own funds in order to get Federal Medicaid dollars, and the Federal Government is slashing its spending, then the total amount available for health and long-term care for vulnerable Americans will shrink even faster.

The results for coverage are devastating. Even if States hold their own Medicaid spending at 1995 levels, the number of Americans who will lose coverage in the year 2002 will not be just 4 million, but 9 million. And I have chart No. 4 which shows in the four States led by the Republican Governors here today, the numbers losing coverage would range from 44,000 in Utah to 313,000 in Illinois and 728,000 from Florida. Obviously, if States decide to reduce their spending below 1995 levels, the loss in coverage would be even greater.

Mr. Chairman, we have many vital issues to discuss today. I hope that we will have a full opportunity to have hearings on what is a major rearrangement of the Medicaid program which—in 5 weeks—we are supposed to recommend to the Congress.

Let's have that proposal on the table. Let's hold hearings on that proposal. Let's get the Governors, these Governors or others, to come back and tell us what they think of those specifics, because that is what we are going to need to do, is adopt specific legislative changes cutting large numbers of Americans out of the Medicaid program, throw them on the rolls of the uninsured—large numbers of people who are poor, and among the most vulnerable in our population. The elderly, disabled, and children are the ones who will be affected.

I would like to ask unanimous consent that I put in a much more extensive opening statement. We have a number of charts. We will make that opening statement and the accompanying charts available to the press and to members of the public, because I think we need to get a full airing of what is at stake in this task before us.

Mr. BILIRAKIS. Without objection.

[The prepared statement and attachments of Hon. Henry A. Waxman follow:]

PREPARED STATEMENT OF HON. HENRY A. WAXMAN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

This is the first of a historic series of hearings. This Committee has been instructed by the Republican majority to report out legislation by July 14 that cuts Federal Medicaid spending by a staggering $187 billion over the next 7 years.

It is hard to overstate the severity of this cut. As you can see from chart #1, under the Republican cuts, in the year 2002, the growth in Federal Medicaid spending would be slashed from 9.3 percent to 1.9 percent. As a result, Federal payments to the States will drop from projected levels by nearly $57 billion, or 32 percent, in that year alone.

In 1996—which happens to be an election year—the Republican cuts are relatively small. But as you can see from chart #2, they quickly explode to unmanageable levels.

Perhaps in order to mask the effects of these massive cuts, the Republican Budget Committee report stipulates that the remaining Federal Medicaid spending be distributed to the States in the form of a block grant.

Under a block grant, over 30 million Americans—more than half of whom are children—would lose their guarantee of health insurance coverage and join the ranks of the uninsured. Over 10 million elderly and disabled Americans would lose their coverage for nursing home and other long-term care.

The Republican Budget Committee's purpose in block granting Medicaid is clear. They want to limit the Federal government's financial responsibility for health care *and* for long-term care. They also want a place in the Federal budget to go to in the future to get large savings for additional deficit reduction or additional tax cuts.

Anyone with any doubt about the fiscal destiny of the Republican Medicaid block grant need only look at the Budget Committee's recommendations with respect to the Maternal and Child Health Block Grant and the Preventive Health Block Grant. These two Block Grants were first established at the request of the Reagan Administration in 1981 and are currently funded at $684 million. The Budget Committee wants them cut by $421 million, or more than three fifths, next year, and then freeze them at that level.

Today's hearing will focus on problems in the current Medicaid program. We can all agree that the Medicaid program is not perfect. In fact, we in this Subcommittee spent the last two years unsuccessfully trying to improve it in the context of health care reform. So it is important that we continue to look closely at the existing program to see where improvements might be made.

But the real issue before this committee is not whether the current program has problems, or what those problems are. The real issue is how in the world the States are going to handle the loss of $187 billion in Federal Medicaid funds over the next 7 years.

In short, what we should be holding hearings on is the specific Republican proposal to block grant the Medicaid program. Unfortunately, we have no concrete legislative proposal before us, even though we have only 5 weeks until we have to report out our recommendations.

Of course, any proposal to take this much Federal money away from the States, and to radically alter an insurer that covers so many Americans, will require careful scrutiny. I hope that the Chairman will reserve at least as much hearing time for his proposal as he has allotted to an examination of the current program.

There are some issues which we can start discussing today, even in the absence of legislative language.

We don't need legislative language to estimate the effect of the proposed cuts on coverage. The privately-funded Kaiser Commission on the Future of Medicaid, using the expertise of health care economists at the Urban Institute, has provided some valuable information on this point.

The Kaiser Commission analysis of the Medicaid cuts that the House Republican budget contains is summarized in chart #3. Under the Republican cuts, even if States hold the growth in spending per beneficiary to the rate of inflation, nearly 4 million Americans will lose Medicaid coverage in the year 2002 alone. In the States represented here this morning by Republican Governors, the numbers of Americans losing coverage would range from over 30,000 in Utah to over 115,000 in Tennessee. In the State represented by the Chairman, the number of residents losing coverage would be over 430,000.

Of course, there is no way to know who those 4 million Americans will be. That's the whole point of the block grant. It is a mechanism that leaves the States with

the burden of deciding whose coverage to terminate. They can choose to eliminate coverage for the elderly, for the disabled, or for mothers and children, or all of the above. But regardless of how efficient they are, unless they replace the lost Federal Medicaid dollars with their own funds, they will have no choice but to cut back on coverage.

It is important to note that the Kaiser Commission analysis assumes that States would continue to spend their own funds in order to draw down Federal Medicaid matching funds, just as they are required to do under current law.

Of course, there is much opposition to that requirement among proponents of block grants. In fact, the policy that the House Republicans adopted in passing their welfare block grant earlier this year relieved States of any spending obligation.

But State spending is a critical part of Medicaid. Obviously, if States are no longer required to spend their own funds in order to get Federal Medicaid dollars, and the Federal government is slashing its spending, then the total amounts available for health and long-term care for vulnerable Americans will shrink even faster.

The consequences for coverage are devastating. If we assume that States need only hold their own Medicaid spending at 1995 levels, then the number of Americans who will lose coverage in the year 2002 will not be just 4 million, but 9 million. Chart #4 shows that, in the four States led by Republican Governors, the numbers losing coverage would range from 44,000 in Utah to 313,000 in Illinois. In the State from which our Chairman comes, 728,000 would lose coverage.

Obviously, if States decide to reduce their spending *below* 1995 levels, the loss in coverage would be even greater.

The other issue we need to start talking about even in the absence of legislative language is the distribution of Federal Medicaid funds among the States.

I will strenuously oppose the dismantling of Medicaid by converting it from an insurer for 36 million Americans into a block grant. However, if the Republican majority prevails on this, we need to look very carefully at whether each State is treated fairly.

A Medicaid block grant would have almost nothing to do with health care or long-term care needs. It would be a fixed amount of Federal funds made available each year to the States—funds with which, as a practical matter, they will be able to do as they please.

What if the Federal Medicaid block grant dollars are distributed on the same basis as Federal Medicaid spending occurs now, and that distribution is frozen into the future? There would be huge variations in Federal payments from State to State, and no adjustments for changing circumstances, like economic downturns or contagious disease outbreaks.

In 1993, the latest year for which comparable data are available, the Federal government spent $291 on Medicaid for every U.S. citizen. In the Chairman's State of Florida, it spent $205 per person. In my State of California, it spent $224 per person. And in the State of Tennessee, it spent $367 per person.

There are 33 States, including Florida and California, where Federal spending per person was less than the national average. In the other 17 States, like Tennessee, Federal spending was above the national average.

As chart #5 shows, if Medicaid is block granted and if the Federal funds are distributed on a historical basis, then 33 States might as well be making annual transfers of billions of dollars to 17 States. A glance at the map (chart #6) shows clearly that the flow of funds would generally be from the West and Midwestern States to the Northeastern and Mid-Atlantic States, although there are exceptions.

This is not an academic point. Over the next 7 years, under the Republican block grant, there would be a total of $768 billion in Federal funds available for distribution among the States. This is potentially the largest resource transfer in the history of the Republic.

I look forward to hearing the views of our distinguished witnesses on these important questions.

Chart #1

Republican $187 Billion Medicaid Cut

House Budget Resolution

	1995	1996	1997	1998	1999	2000	2001	2002
CBO Baseline	89.2	99.3	110	122.1	134.8	148.1	162.6	177.8
Annual % Growth		11.3 %	10.8 %	10.9 %	10.5 %	9.9 %	9.8 %	9.3 %
Republican Baseline	89.2	96.4	101.7	105.7	109.9	114.3	118.9	121.2
Annual % Growth		8.0 %	5.5 %	4.0 %	4.0 %	4.0 %	4.0 %	1.9 %
Cut in Federal Funds		-2.9	-8.4	-16.3	-24.9	-33.8	-43.7	-56.6
Percentage Cut		- 3.0 %	- 7.6 %	- 13.4 %	- 18.5 %	- 22.8 %	- 26.9 %	- 31.8 %

Chart #2

The Republican Medicaid Cuts: $187 Billion Over 7 Years

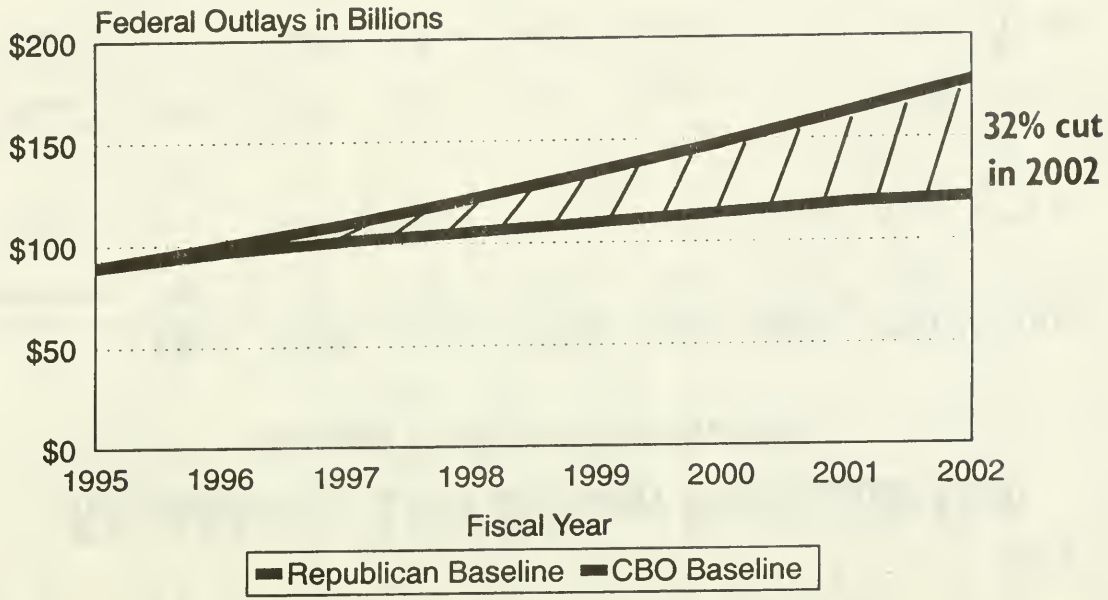


Chart #3

Republican $187 Billion Medicaid Cut

Coverage Losses in 2002
If States Must Continue to Match

Florida	432,000
Illinois	82,800
Michigan	55,000
Tennessee	114,700
Utah	30,500

???

Chart #4

Republican $187 Billion Medicaid Cut

Coverage Losses in 2002

If States No Longer Need to Match

Florida	728,000
Illinois	313,000
Michigan	225,000
Tennessee	221,000
Utah	44,000

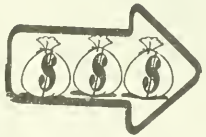
???

Chart #5

Republican Medicaid Block Grant

Federal Dollar Transfers

AL, AZ, AK, CA, CO, DE, FL, GA, HI, IA, ID, IL, KS, MD, MI, MN, MO, MT, NE, NM, NV, OH, OK, OR, PA, SD, TX, UT, VA, VT, WA, WI, WY



AR, CT, IN, KY, LA, MA, ME, MS, NH, NC, ND, NJ, NY, RI, SC, TN, WV

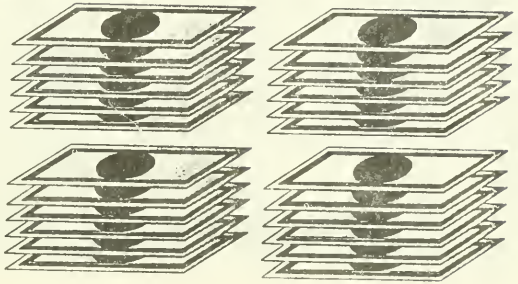
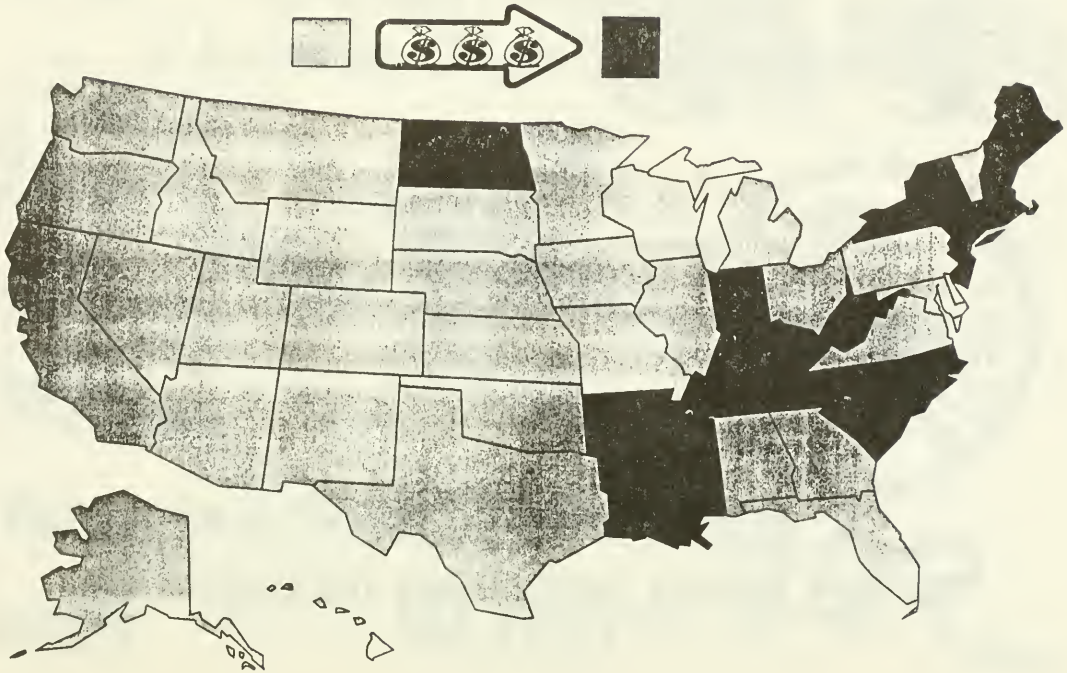


Chart #6

Republican Medicaid Block Grant

Federal Dollar Transfers



Mr. BILIRAKIS. And without objection, the opening statements, as I announced previously, of all of the members will be made a part of the record.

[The prepared statements of Hon. Thomas J. Bliley, Jr., Hon. Fred Upton, Hon. Cliff Stearns, Hon. Richard Burr, Hon. Brian P. Bilbray, Hon. Greg Ganske, Hon. Charlie Norwood, Hon. Frank Pallone, and Hon. Mark Foley were received for the record:]

PREPARED STATEMENT OF HON. THOMAS J. BLILEY, JR., CHAIRMAN, COMMITTEE ON COMMERCE

I want to welcome our distinguished witnesses. The Governors know first hand the problems with the Medicaid program. The program is consuming an ever increasing portion of State budgets, there is no more complicated Federal program, HCFA micromanages every aspect of the program, and the only way a State can be given any flexibility is to file a voluminous waiver application which HCFA may or may not approve after months of review.

By voting for a balanced budget and the budget resolution, Congress has made a commitment to making major changes in the Medicaid program. As we all know, the Medicaid growth rates have been astounding, growing at an average annual rate of 19.1% between 1990 and 1994. During 1991, Federal Medicaid outlays grew by 27.8 percent. They grew another 29.1 percent in 1992. For the current Fiscal Year, the Congressional Budget Office (CBO) estimates that Federal payments will be $89.2 billion, and State payments will be an additional $67.3 billion, for a total of $156.5 billion. Medicaid expenditures are expected to rise faster than other health expenditures through 2002. CBO projects Federal Medicaid payments rising by 11.3 percent in Fiscal Year 1996, moderating slightly to an increase in 9.3 percent in Fiscal Year 2002.

We must slow the annual growth rate. Medicaid expenditures can no longer grow at two or three times the consumer price index.

We can constrain the growth rate by giving our nation's Governors the flexibility they need to create and administer innovative health care programs. Medicaid is out of sync with the rest of the health care system. There are no incentives for beneficiaries to receive primary and preventive care. Many Medicaid beneficiaries continue to receive their medical care in hospital emergency rooms where the cost of their treatment is enormously more expensive. Clearly, a better designed system will not only save money but provide beneficiaries with a higher quality of care.

To achieve this result, the Committee will look at a proposal to convert the current Medicaid program into a system of block grants to the States. The proposal would look to constraining the growth of Federal outlays for Medicaid by managing them under a capped block grant approach. Under the block grant approach, States will have the flexibility to create innovative health programs for their low income citizens.

Although tremendous flexibility will be given to the states so that each State can design a program which best fits its citizens, there will still be a necessary and important role for the Federal government in terms of oversight. Federal oversight is essential to ensure that states continue to contribute their current financial share of the program.

I am anxious to hear the testimony of our witnesses and look forward to working with you in developing a better Medicaid program.

PREPARED STATEMENT OF HON. FRED UPTON, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MICHIGAN

Thank you, Mr. Chairman. Medicaid. One word that strikes fear into the hearts of State governors tasked with balancing their budget; Anger in the minds of providers who feel they are under-reimbursed; and hope in the spirit of the poor who desperately need this program.

Unfortunately, the poor don't get the care they need until they are extremely sick; the providers can't financially care for those they have sworn their Hippocratic oath to serve; and Governors are forced to spend even more and more taxpayer money for less and less service. Something must be done.

All of the Governors here today have faced the Medicare problem in their states. Some Governors, like Governor Sundquist of Tennessee, have inherited programs created under the 1115 waiver process. Others, like the Governor of my home state of Michigan, have chosen a different route.

While Governor Engler has not applied for the 1115 waiver, he has been at the forefront of innovating the Medicare program. Under Governor Engler, the Medicaid eligibility level for pregnant women has been set at 185% of poverty. This move has meant that 50,000 births have been paid for by Medicaid, compared with 33,600 in 1985. The federal mandate, which Michigan has surpassed, is 133% of poverty.

Federal mandates are a good example of why Michigan's Medicaid program is spiralling out of control. According to the Mackinac Center for Public Policy, $95 million will be required to meet the federal mandates imposed on Michigan. In less than two years, if this program is not fixed, federal Medicaid mandates will equal 30% of Michigan's general revenue.

For these reasons, I welcome Governor Engler and the rest of the Governors for this very important hearing, and I yield back the balance of my time.

PREPARED STATEMENT OF HON. CLIFF STEARNS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF FLORIDA

I would like to thank Chairman Bilirakis for holding this first in a series of hearings on the transformation of the Medicaid program.

Medicaid is a joint federal-state program that pays for medical services on behalf of low-income persons. In my home state of Florida, Medicaid provides coverage to approximately 1.6 million people.

Since Medicaid is projected to continue growing by about 10 percent a year over the next five years, we must take some bold steps to keep the program from spiraling out of control. In fact, the federal share for Medicaid is projected to be $619.7 billion for fiscal year 1996 through fiscal year 2000. Assuming an average state match of 43 percent, it is estimated that the state share will be $467.3 billion over that same five year period.

With such statistics, the need to control the rate of growth of this program is all too apparent. It will be not an easy task. The changes we make could have a tremendous impact on not only the beneficiaries but many of the providers, including hospitals. Therefore, in addition to preserving the current program, we must ensure there is sufficient funding to meet the needs of those being served by this important program.

I am especially pleased that we will be hearing from Governors representing states from several different regions of the country. I would like to give a special welcome to Florida's Governor Lawton Chiles. It is nice to have Mr. Chiles here with us today. By having each Governor give us his perspective on what needs to be done, and hopefully, to make recommendations based on what works and what doesn't, we will be provided with a groundwork from which to proceed.

Since Florida has been ranked in the bottom 10 in Medicaid cost or $2,368 per recipient compared to New York which receives $6,402 per recipient, if we block grant this program with a 5 percent cap on annual increases using the current formula it would be detrimental to the state of Florida. We must change the current formula to insure that Florida is not penalized for providing health care in a cost efficient manner.

Under the current formula per capita income is used as a measure of the states' ability to finance program benefits. It further assumes that low income states experience a greater incidence of poverty. Thus, states like Florida with a weak tax base and high concentration of low-income people are underfunded. There are several primary considerations which must be addressed when corrections to the federal Medicaid matching formula are made. First, we must adjust the growth cap for population. This is a chief concern since Florida is a high growth state. Second, there must be a provision to have a transition to national rate by variations in state costs.

Since the Governors are responsible for administering this program, I am anxious to hear from them directly how they would streamline the system.

Thank you again for being here today.

PREPARED STATEMENT OF HON. RICHARD BURR, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NORTH CAROLINA

Thank you Mr. Chairman. I appreciate this opportunity to hear from our distinguished panel of Governors and look forward to working with them to craft a formula for the Medicaid program which will appropriately address the needs of all our states.

My immediate concerns are two-fold, although I am sure they will expand considerably over the hearings we will hold in the coming weeks. First, I am concerned about the exorbitant growth rate of the Medicaid program, particularly when it is

compared to private sector insurance. Hopefully, by eliminating the umbrella of federal bureaucracy and allowing states to meet their geographic and demographic needs, a more business-minded, higher quality and more effective welfare related health services program will result. We have seen many innovative and cost saving programs that have been developed in cities and states across the country, and the purpose of block grants is to provide states with the ability to craft creative solutions to a problem which is becoming more and more expensive to address.

My second concern relates to states like my state of North Carolina, which is considered a high-growth state. Certainly it is not appropriate to penalize states whose policies have encouraged healthy economic growth and increased numbers of seniors who are often Medicaid beneficiaries. I am concerned that many of the formulas which have been proposed do not fairly address the needs of states like North Carolina, and I look forward to working with my governor, Jim Hunt and others across the country to create a program which will equitably meet the needs of all our states.

Again, welcome to our governors and thank you for bringing your ideas to the table for discussion.

PREPARED STATEMENT OF HON. BRIAN P. BILBRAY, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Mr. Chairman, I commend you for beginning this series on the Medicaid system by leading off with those that have hands on, practical, experience with administering federal programs—the governors from across the nation.

As we begin the debate on Medicaid, I would like to discuss for a moment the unique situation that exists in my state of California.

California ranks 48th in its per person expenditures, while other states are spending up to four times as much per person. California's program, Medi-Cal, is cost-effective and operates in a highly competitive marketplace.

It achieves tremendous program savings with its selective provider contracting program which has been in place since 1982. In 1993-94 alone, it estimated a net savings of approximately $565 million which is the difference between negotiating rate payments and cost-based reimbursement.

In all age groups, Medi-Cal costs per enrollee are lower than nationwide costs. For example, in the: Funding for children, $601 Medi-Cal dollars are spent versus $955 per enrollee in other states; Funding for adults ages 21-64, $1,422 Medi-Cal dollars are spent versus $1,717 per enrollee in other states; Funding for the disabled, $4,641 Medi-Cal dollars are spent versus $7,216 per enrollee in other states; and Funding for the elderly, $4,929 in Medi-Cal dollars are spent versus $8,704 per enrollee in other states.

The Medi-Cal program has generated $22 million in savings since 1993 through its private insurance premium payment programs (Health Insurance Premium Payment and Employer Group Health Plan). These programs pay private premiums for Medi-Cal eligible persons who need high-cost medical care.

In regards to managed care, Medi-Cal has been involved for over 20 years and is constantly testing and improving many models. Over 400,000 of those eligible for Medicaid are already enrolled in managed care plans. Another two million will be enrolled in the next 18 months under a strategic and innovative program.

The successes and strides that California has taken should be emulated by other states and used as a model for their own programs. Any formula being considered for a block grant *should not* punish these successes. In addition, any capitation should take into consideration the poverty and SSI growth rate of the state. California's state Medicaid expenditures have grown from $4 billion in 1991 to $6 billion in 1995. They are expected to grow to $10 billion by the year 2000. Any block grant formula should take these staggering statistics into consideration.

As a former county supervisor, I realize the need to give state and local governments more authority over programs. Therefore, I am fully supportive of the block grant proposal, which will provide greater flexibility to the states to implement innovative and cost effective programs.

I look forward to hearing the testimony of the governors and for a continued dialogue with them on this critical issue. In addition, I would like to submit testimony of Governor Pete Wilson from my state of California, and associate myself with his comments. Again, thank you for holding these important hearings on Medicaid.

PREPARED STATEMENT OF HON. GREG GANSKE, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF IOWA

Mr. Chairman, thank you for calling this important hearing today. As you have noted, this will be the first of many hearings this panel holds in reviewing the Medicaid program.

This unique federal-state partnership provides critical health care services to millions of Americans. Contrary to popular belief, Medicaid is more than health care for poor Americans. The program also assists millions in meeting the costs of long term care. Though a minority of program participants, elderly beneficiaries in long term care facilities consume a majority of Medicaid resources.

Unfortunately, these programs have grown far faster than the rate of inflation. Much has been made of the recent report of the Medicare Trustees noting the years of 10 percent annual growth will result in the bankruptcy of Medicare Part A. And although Medicaid does not face a similar bankruptcy, it has also experienced unsustainable rates of growth which have strained the ability of both state and federal governments to meet program needs. The fiscal consequences of failing to deal with skyrocketing Medicaid expenses is just as serious as the impending bankruptcy in Medicare.

At the same time, I have strong concerns about the shape of Medicaid reform plans which do not address the funding disparities in the current system. In the past, some states have "gamed" the Medicaid system to generate larger and larger federal payments. Often these funds were put to non-medical uses. As a result, Medicaid reimbursements in some states are two or three times higher than those in other areas of the county. I hope that our Medicaid reform plan will not constitute a Congressional Seal of Approval of the inequities of the past.

Today, as we begin to review options for reforming the Medicaid program, we will hear from some of the nation's most distinguished Governors. I look forward to hearing from them on ways that we can constrain the growth of this program without maximizing federal resources.

In Iowa, Governor Terry Branstad has been a leader in developing innovative solutions for the delivery of social services. In a letter to me dated June 6, he raised a number of important issues which we must address in any Medicaid reform efforts. I think his observations would be instructive to my colleagues and ask unanimous consent that a copy of his letter be placed in the record.

Mr. Chairman. Thank you again for calling this important hearing. I look forward to the testimony of the witnesses today and to working with them and all of my colleagues in drafting a more efficient and effective Medicaid system for the next century.

OFFICE OF THE GOVERNOR,
DES MOINES, IOWA,
June 6, 1995.

The Honorable GREG GANSKE, M.D.,
United States Representative,
1108 Longworth House Office Building,
Washington, DC.

DEAR CONGRESSMAN GANSKE: I want to thank you for your active role in addressing the reinvention of the respective roles of the federal and state governments in meeting the needs of low-income Americans. I am delighted by the commitments of Congress to balance the budget, to simplify programs, to eliminate duplication and waste, and restore to the states opportunities for restructuring programs to best serve their citizens.

I have supported the efforts of you and your colleagues in the House of Representatives. They have shown great leadership and courage in developing and passing reform legislation across a broad range of human service programs. I believe the Senate will work to further refine legislation with the goal of empowering states to determine and manage the delivery of public services.

In my recent testimony before the Senate Agriculture Committee, I included the following remarks: "Most states recognize that you can not truly reform the current system by simply changing one program. We must look to all programs. That includes, but is not limited to AFDC, JOBS, Child Care, Child Protection, Child Support, Medicaid, and Food Stamps. If you do not take steps to reform and link these programs, states cannot fully succeed in their reform efforts. This includes state authority to transfer up to 30% of block grant funds in either direction between block grants."

The House of Representatives has taken a major stride towards reforming and linking these programs. There is an additional critical step that must be taken and I am writing to urge your support in moving in that direction: a block grant for Medicaid.

Iowa has become a leader in managed health care. On March 1, 1995, a statewide managed mental health care program was implemented in Iowa—perhaps the first statewide program in the nation. This year, a managed care system for substance abuse treatment will be implemented.

I believe Iowa has proven its commitment and creativity in serving many populations: children, the disabled, and families. I ask your help in assuring that Medicaid is not left out of the block grant strategy that seeks to empower states, simplify programs, eliminate waste, and synergize programs that have too long operated in fragmented ways.

Let me share with you a few of the Medicaid issues that must be addressed:

1. *Cost-shifting*—The intent of the Disproportionate Share program for hospitals (DSH) was sound. It has been used, however, as a mechanism to shift costs from the states to the federal government. On the other hand, we urge you to guard against a shift of costs from Medicare to Medicaid such as that which burdened Iowa when the Catastrophic Health Care Act was repealed. The state/federal partnership ought to focus its strategies toward improved health care outcomes, not cost-shifting as illustrated in these two examples.

2. *Program complexity*—The current Medicaid program is enormously complex. Despite best efforts of staff in the field and in administration, it has become almost impossible to explain the program to clients or providers. For example, a single household may have some persons eligible at 100% of poverty, others at 133% of poverty, and yet others at 185% of poverty. In this same household, income and resources may have to be calculated differently to determine the eligibility of the individuals, children and adults, who are a family unit. We need the ability to set eligibility criteria.

3. *Cost containment*—When federal statute required states to reimburse Federally Qualified Health Centers at full cost, there was no accompanying incentive for these providers to contain costs. The rate of reimbursement in Iowa went from $30 to $70 almost overnight. The Boren Amendment, intended to allow states to move away from cost reimbursement, has turned out to be an undefined minimum threshold that has given providers a vehicle for litigation against the states. These are but two examples of how policy at the federal level needs to be looked at closer to avoid unintended results. States are in a better position to know how to blend fair reimbursement policy with cost containment. Iowa has demonstrated an ability to control its Medicaid rate of expenditure growth. This has benefited both the state and the federal government.

4. *Flexibility*—It is essential that we avoid a capped entitlement program for Medicaid. With a limit on the growth of federal funds, it is essential that we have flexibility in designing a program of cost-effective services and establishing eligibility criteria for the populations to be served.

I urge you to continue your strategy of block grants aid extend it into the crucial arena of Medicaid and Medicaid-related services. I assure you that Iowa will redouble its efforts to structure programs in a manner that will achieve maximum health care access for vulnerable populations.

I thank you, again, for your hard work. I would be happy to assist you in any way I can as we mutually strive to serve this state and set a new direction for the nation.

Sincerely,

TERRY E. BRANSTAD,
Governor.

PREPARED STATEMENT OF HON. CHARLIE NORWOOD, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF GEORGIA

Mr. Chairman, thank you for calling this hearing on transforming the Medicaid program. I realize we have our work cut out for us. Budget resolutions have a way of doing that.

I look forward hearing from the esteemed Governors of Illinois, Michigan, Utah, and Georgia's neighbors Tennessee and Florida. I know these men are on the front lines and have to deal on a daily basis with the many mandates that have been placed on them by the federal government. At the same time, I am sure they share the same concern with us that the country faces bankruptcy with mounting deficits and we must find savings within Medicaid and Medicare.

As the proposal to place the Medicaid program into block grants goes forward, I know it will be the governors that will need to be the entrepreneurs who will bring needed innovation to the system. I am anxious to hear their thoughts on that issue.

Mr. Chairman, in hope that our expertise on this issue will increase exponentially, as a result of today's discussions, I yield back the balance of my time.

PREPARED STATEMENT OF HON. FRANK PALLONE, JR., A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW JERSEY

Thank you, Mr. Chairman. I understand that this is going to be the first of about six hearings on the Medicaid program to determine what changes should be made to improve the system. In addition, I feel that it is appropriate to have four distinguished Governors on the first panel, since this program will have a huge impact on every state.

It is obvious that the Medicaid program faces many challenges and is in need of some re-tooling to improve coverage, maintain quality services, and hold down costs. At the same time, I also support increased state flexibility in providing appropriate levels of care to those who benefit from this program. However, I *do not* believe that the block grant proposal from the House budget resolution is the answer to reforming Medicaid.

Now I understand that the Republican Congress is pursuing a balanced budget, and I applaud that effort, but I *do not* believe that arbitrary cuts are the answer. It appears that the direction we are headed is towards block granting Medicaid with strict caps on funding provided by the federal government to the states. These proposed caps in federal spending will reduce services to individuals who benefit from Medicaid. As with Medicare, I believe that Medicaid should be reformed, but in the context of health care reform.

It is my hope that these hearings will be the vehicle to educate the public about who really benefits from this program. I feel that many see Medicaid as a program that primarily benefits the poor. In fact, one-third of the spending from Medicaid provides benefits to senior citizens, especially in obtaining long-term care, such as nursing home care. Another third of the funding assists those who are disabled or blind. As the program is currently structured, by the beginning of the next decade, every child and pregnant woman will receive health care services-universal coverage for children. My fear is that by making the proposed cuts in this program, many of these people will see a reduction in their health care services, and may not even continue to receive health benefits.

This would create a tremendous strain on the health care system in America and on my home state of New Jersey. If the caps are enacted, New Jersey stands to lose close to $4 billion dollars in federal funding and by the year 2002 will see a cut in its current projected funding by about 25 percent. This is a large cut to swallow, even if New Jersey could creatively come up with every innovative method to reduce the costs of providing the same level of health services.

Over one million senior citizens in New Jersey receive assistance from Medicaid and I do not want them to have to take these cuts, when more cuts are expected when we consider Medicare. Many are receiving long-term care and nursing care through the Medicaid program. These seniors are not taking a free handout. Most worked and paid taxes all of their lives and due to circumstances of aging, they required long-term care services, which are very expensive. Without Medicaid, many in my generation would have to find ways to pay for our parents' long-term care needs. Without Medicaid, it is our middle-class that will suffer. New Jersey's Medicaid population is near 8 million people including: senior citizens, children, pregnant women, disabled, blind, and indigent.

During this hearing, I will be interested in hearing each Governor's ideas on how their state will operate under a capitated Medicaid block grant program. Each of our states will see a drastic reduction in the amount of funding that the federal government will provide for Medicaid and I am eager to hear how Medicare will continue to operate with the same level of services that is currently offered. In addition, I am eager to learn if the states will continue to be required to make a matching contribution to the Medicaid program. I am concerned that states may not be required to match the federal dollars, thereby further decreasing needed health services for our seniors and our children.

As more hearings ensue, I will be interested to learn what method of funding distribution will be employed for every state because I am very concerned that New Jersey may receive a disproportionate share of funds based on the number of beneficiaries served. In addition, I have reservations about the increased negative impact a recession would have on my state in a capitated system. If more become unem-

ployed, without an increase in Medicaid funding, then it basically means that less will be able to utilize appropriate health services.

Mr. Chairman, I am very distressed with the potential impact our actions will have on my constituents and on every American. I hope that any reform that is reported out of this subcommittee continues to benefit those in need.

Thank you, Mr. Chairman, and I yield back the rest of my time.

PREPARED STATEMENT OF HON. MARK FOLEY, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF FLORIDA

Mr. Chairman, I want to thank you for allowing me the opportunity to submit this testimony for the record.

The 104th Congress is faced with a difficult task of balancing the federal budget by the year 2002. Our national debt is approaching 5 trillion dollars—a figure that is rapidly growing each year. According to the Bipartisan Commission on Entitlement and Tax Reform, projected outlays for entitlements and interest on the national debt alone will consume all tax revenues collected by the government in the year 2012 if we fail to cut federal spending. This is a dismal forecast for our children and grandchildren who will invariably suffer the financial consequences unless Congress takes appropriate measures to restore accountability to the budget process.

Therefore, it is incumbent upon Congress to formulate responsible policies, including structural reforms of entitlement programs. One of these proposals being considered is block granting Medicaid to the states. The federal, state and local cost of Medicaid in Fiscal Year 1993 was $130 billion and is expected to reach $300 billion by the year 2000. This program has become one of the fastest growing segments of federal and state budgets. This rate is clearly unsustainable.

I support the Subcommittee's efforts to address this problem and develop a proposal that would provide states with greater flexibility for the implementation of the Medicaid program. However, as this process continues, I encourage the Subcommittee to take into consideration the unique concerns of high-growth states.

Florida's population continues to grow at a rate twice the national average. My home state experienced the second largest growth rate among the largest states between 1992 and 1993 and is expected to experience the third largest net increase in population between 1993 and 2020. Florida's elderly population also is growing faster than in other states and ranks first in the percentage of the population 65 years and older.

In addition, the growth in Medicaid service expenditures has more than doubled in the last five years which is largely attributed to the increase in the elderly population and their need for long-term care covered by the Medicaid program. While this has placed a significant strain on Florida, the state has managed a smaller than average Medicaid program in terms of how much money is spent on each enrollee. State expenditures have been much lower than the national average, ranking 43rd in the nation in 1992—only seven states had lower costs per Medicaid recipient.

In 1993, the U.S. General Accounting Office (GAO) conducted a study of the current Medicaid funding formula and concluded that under the current formula, it does not target most federal funds to states with the greatest needs—those with weak tax bases and high concentrations of low income people. Therefore, high growth states like Florida receive a disproportionate share of federal funds. This is unfair and needs to be rectified to ensure that a block grant does not place an undue burden on Florida taxpayers.

Mr. Chairman, I want to respectfully impress upon the Subcommittee the need to closely examine the formula inequity. As we work together on developing fiscally responsible policies, I hope that states will equally share this responsibility.

Mr. BILIRAKIS. I announced earlier that Messrs. Dingell and Bliley, in addition to the chairman and ranking member, would have an opportunity to make opening statements and would now call upon Mr. Dingell.

Mr. DINGELL. Thank you, Mr. Chairman. Mr. Chairman, I commend you for holding these hearings.

Today, the committee begins its process to explore the important subject of whether to convert one of the most important Federal health care programs, Medicaid, into block grants to the several

States. In the last Congress, we explored the means to expand coverage of health care to millions of uninsured Americans. This year our efforts seem to be directed in different directions, that is, finding ways to reduce coverage while increasing the number of uninsured.

The political logic behind block grants is unassailable. The Federal Government collects the taxes and we get the people all angry with us, while the States dispense cash and favors with largesse, that is wonderful to behold, with no strings attached. They get the credit and we get the grief. I hope there is more than political logic at work here.

My home State of Michigan has proposed that with block grants there will be no State maintenance of effort. In other words, the State of Michigan would receive Federal checks from the Federal taxpayer and have no obligation to provide its own money to help pay for health or for long-term care.

The mathematics of the proposal are again curious. It appears that Michigan is willing to allow the Federal share of Medicaid dollars to be limited to an average growth rate of just 4 percent for each of the next 7 years while the number of Michigan residents eligible for Medicaid is projected to grow by nearly 10 percent annually over the next 7 years.

How this increase will benefit us and how we will be benefited by the situation in which long-term health care and long-term health care benefits will change when in the year 2002 alone under the plan before us Michigan would lose nearly $2 billion in Federal funds. This constitutes a clear annual reduction of more than 30 percent. These are serious concerns.

And Michigan is not alone. But for Michigan this may mean that more than 16,000 residents would lose their eligibility for Medicaid long-term care benefits in 1996. A number that would grow to 174,600 people by the year 2002.

This is not a problem that can simply be cast off on the poor. Because it is going to affect a lot of other people. Without Medicaid, hard-working, middle-class families in Michigan with a parent who needs long-term care will face nursing home bills of at least $38,000 each per year. About 40,000 mothers and children will also lose coverage. I remind all that more than 60 percent of the children receiving Medicaid benefits in Michigan have at least one full-time working parent.

Let me not be a naysayer here. I am sure my Governor before embarking on one of the greatest social experiments ever conducted by Congress will want to see to it that we know the details of how consumers of health care benefits will be protected and how shortfalls in health care spending will be met and how these supposed efficiencies can be achieved. I am sure that he and other Governors today will be prepared to provide us with details on how these proposed savings can be achieved without removing coverage from those vulnerable individuals who are currently covered.

As my colleagues will appreciate, our job here is not just to focus on what is good for our individual State but what is good for the Nation as a whole. Maybe it is perfectly acceptable to allow residents of one State to receive less per benefit than residents of another State or for children with certain conditions to be covered in

one State while children with those very same conditions in another State must go without health care. Much of what we are talking about today presumes that the States will be willing and able to provide adequate health care for their residents.

But it is indeed curious that the States say that a reduction in billions of dollars from the Federal Government will not translate into reduced coverage for millions of Americans. If the intent here is to reduce health care coverage, then the proponents of the proposal should at least have the coverage and the willingness to say so. They say that in the land of the blind, the one-eyed man is king.

What we are contemplating here today may jeopardize both the quality and quantity of health care coverage to millions of Americans. We are trading a system that is flawed but at least guarantees for millions of Americans for years a system that appears to guarantee absolutely nothing. We are doing this on the basis of the vaguest of assertions from the States without any evidence of what the legislation is that we are beginning to address is going to look like and we are operating in the blind here. But I see no kings among us.

Thank you, Mr. Chairman.

Mr. BILIRAKIS. I thank the gentleman.

Mr. Bliley is not with us. Therefore, we will get right on to the witnesses before us to the panel. I would recognize very briefly, Mr. Hastert of Illinois, who wants to say something nice about his Governor.

Mr. HASTERT. I thank the chairman. I will be brief. But I just want to thank you, Mr. Chairman. It is indeed a pleasure to honor and to introduce our Governor today from the great State of Illinois, Jim Edgar.

Governor Edgar has certainly earned a reputation and as a respected Governor who has brought new fiscal discipline to State government. Last November, the folks in Illinois showed that when they reelected him by the largest margin of any other Illinois Governor in this century.

He has worked with me over the years to try to bring some fiscal responsibility to a lot of areas in State government, but Governor Edgar is here today because he is the Chairman of Republican Governors' Association's task force on Medicaid. We have had some problems in the State of Illinois with the present system. It doesn't work. Our Governor has put a lot of time and hard work into examining the Medicaid program.

I look forward to hearing his insights today during our hearing, and I very much appreciate the opportunity to introduce him.

Mr. BILIRAKIS. I thank the gentleman. Mr. Upton, would you like a moment or two?

Mr. UPTON. Well, thank you, Mr. Chairman.

I, too, would like to welcome my Governor who has done yeoman's work in terms of turning our State around from having a massive deficit to one where we can actually cut taxes in a major way.

Obviously, Medicaid is something that we need to take a very good look at it. Federal mandates, in fact, are one of the reasons why Michigan's Medicaid program has been spiraling out of control.

We have a think tank in Michigan called the Mackinac Center for Public Policy and they have estimated that $95 million will be required to meet the Federal mandates imposed on Michigan in this year, and in fact in less than 2 years if the program isn't fixed Medicaid mandates will equal 30 percent of Michigan's general revenue. Because of those alarming statistics, I am delighted that the chairman allowed me to make sure that our Governor participated in the panel and I look forward to his testimony and the dialog that all of us will have with each of the five Governors.

Mr. BILIRAKIS. I thank the gentleman and I take pleasure on behalf of the other two Floridians on this panel to welcome Governor Chiles, a man with whom I worked very closely when he was in the Senate up here on a very, very bipartisan basis. We spent an awful lot of time together, Governor, you and I and our staffs, on this Medicaid situation on behalf of the State of the Florida. So it is really great to have you here and, of course, we welcome all the Governors and particularly our former colleague, Mr. Sundquist, a man who we have spent many times, many, many hours with at all hours of the night, I might add, up here.

Congratulations. Welcome to all of you. Your entire statements of course will be made part of the record.

I would appreciate if you can keep your oral statements to as close to 10 minutes as possible and we will start off with Governor Edgar.

STATEMENTS OF HON. JIM EDGAR, GOVERNOR, STATE OF ILLINOIS; HON. LAWTON CHILES, GOVERNOR, STATE OF FLORIDA; HON. DON SUNDQUIST, GOVERNOR, STATE OF TENNESSEE; HON. JOHN ENGLER, GOVERNOR, STATE OF MICHIGAN; AND HON. MIKE LEAVITT, GOVERNOR, STATE OF UTAH

Mr. EDGAR. Thank you, Mr. Chairman and members of this important subcommittee, particularly my Congressman. Congressman Hastert, thank you, for those kind words.

I greatly appreciate the opportunity to testify before you today. You are focusing on an issue of tremendous importance to you in the Congress, to every Governor in this Nation, and to the people we all serve.

We must boldly reform the way in which health care is provided to low-income families and individuals. The Medicaid system is out dated and out of control. Its skyrocketing price tag has played havoc with State budgets across this Nation for years and years. And it will play havoc with bringing the Federal budget into balance unless we overhaul it. Not tinker with it. Not adjust it. Incremental reforms have been tried and it is simply not enough. The reform also must be sweeping and must come quickly or we will totally lose our capability to provide health services to the truly needy, particularly poor children at an manageable cost.

Medicaid now ranks as the third largest entitlement program of the Federal Government. Only social security and Medicare top it. Without sweeping reform, the Federal Government estimates that Medicaid's annual cost will soar to $260 billion by the year 2000, as this chart over here shows. In other words, it will double over the next 5 to 7 years. And the growth in this program already has been mind-boggling, not to mention budget-busting.

Consider this. Medicaid accounted for 10 percent of total spending by State governments in 1987. Today, it consumes twice that. The Federal Government has micromanaged the program by heaping mandate after mandate upon States. It has told us whom we must serve and dictated how we must provide the service without regard to cost. In 1966, the first year of Medicaid, Illinois spent $87 million on the program. This year, we will spend 64 times that much, or nearly $6 billion.

In Illinois, the tab for recent Federal mandates alone tops $480 million this year. This chart shows the steep increase in Medicaid costs in the last few years in Illinois compared to AFDC, which a lot of discussion has been given to. Medicaid is where the growth has been. In fact, because of those mandates and rising health care costs, we have increased spending for Medicaid between 1991 and 1995 more than we were able to boost funding for education, child welfare, prisons, mental health, and law enforcement combined. That is right, for Medicaid, more for Medicaid than for all those other vital, worthwhile programs and services combined.

There is something very wrong with this picture. It is not the picture we wanted. It is the one that was forced upon us as we sought to balance our State budget while living within our means. I would have preferred to spend more on education, more on mental health, more on law enforcement. But we had much more control and far less government interference in setting budgets for education and other services outside the Medicaid realm.

The Governor of any large, industrial State could give you comparable testimony. This is not a partisan matter. Republican and Democrat Governors alike have been grappling with this failed system and I can't imagine how anyone can defend it.

We need to bring some fiscal sanity to the Medicaid program. And the only way we can do it is through a total revamp, a revamp that will allow us to deliver care to the neediest of our citizens without bankrupting the States and the Federal Government.

We need to cure Medicaid of its various financial and bureaucratic ailments. And this dramatically different Congress can produce the right medicine. You need to take the bold steps that are needed. Get the Federal Government out of the business of micromanaging Medicaid. Let the States make Medicaid more cost effective. Let us innovate without coming hat-in-hand to Washington seeking waivers from the Medicaid mandates. It simply has taken too long to get relief from entrenched, unelected, and unaccountable bureaucrats who fight change. And when reform has come, it has been piecemeal at best.

Unfortunately, I have experienced firsthand the frustration of trying to reform Medicaid through the waiver process. Last July, I signed into law legislation to create a managed care program in Illinois. It was a product of a consensus that few believed we could reach in Illinois. Health care providers, advocates for Medicaid clients, Republicans and Democrats in the legislature, all supported the new law.

Of course, we needed a Federal waiver to implement it. We made the request in September. Since then, HCFA has delayed and delayed and delayed. The bureaucrats ask questions. We rush to respond. And then we wait and wait. The bureaucrats then ask more

questions. More quick responses and still more waiting and waiting. But no action.

This stack of papers in front of me makes up the copies of every single piece of paper required by HCFA concerning our waiver requests. Nine months of waiting. A pile of paperwork and still no waiver.

Millions of dollars that could have been saved to Federal and State taxpayers have not been saved. President Clinton felt the frustration as Governor and he as President has told the Governors time and time again he wants the waivers to come quickly. We were listening but the bureaucrats apparently weren't. They would rather fiddle and quibble.

Clearly, Medicaid as it exists today is a broken system and the cumbersome waiver process is only part of the problem. The Federal Government has dictated benefits that are far more generous than normally provided to working men and women through private insurance programs. In fact, in Illinois we recently made a decision to forego Federal matching funds for some alcoholism and substance abuse treatment programs because it would be more cost effective for us to manage the program under our own rules.

Moreover, under the current Medicaid system, States cannot limit access to health care providers as a means to negotiate the best rates possible. In stark contrast, virtually every private insurer limits the choice of providers under preferred provider arrangements or managed care plans. The States should be able to operate like any large insurer and negotiate the best rates with only the number of providers necessary to deliver the service. And we should be able to negotiate those rates free of the threat of lawsuits posed by the Boren amendment.

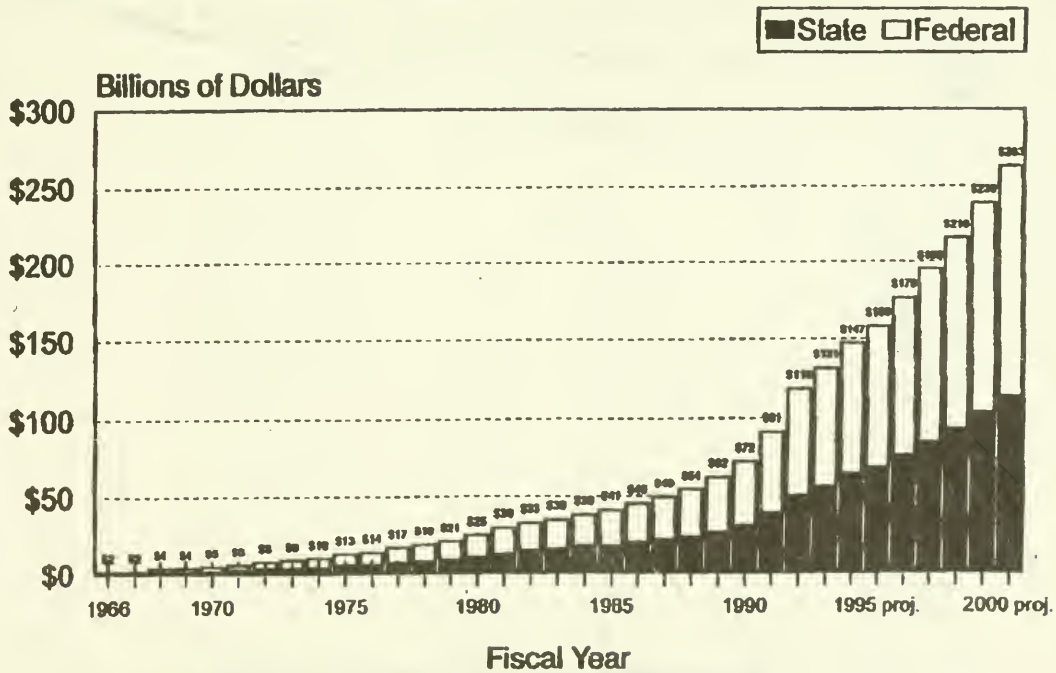
The amendment was well-intentioned. It was to provide a ceiling for provider's rates. But the Federal courts have interpreted it as a floor and put States on the defensive, costing them hundreds of millions of dollars every year. It is difficult to drive a hard bargain when the providers believe they can steer the dispute to the Federal courts.

We need to repeal the Boren amendment. We need to do that and much more to reform Medicaid. Clearly, the taxpayers of this Nation cannot afford to pay the skyrocketing costs of a broken system and therefore it ultimately will fail the needy who rely on it for benefits. Massive reform has long been overdue. It needs to happen now. And we as Governors look forward to working with you to make it happen.

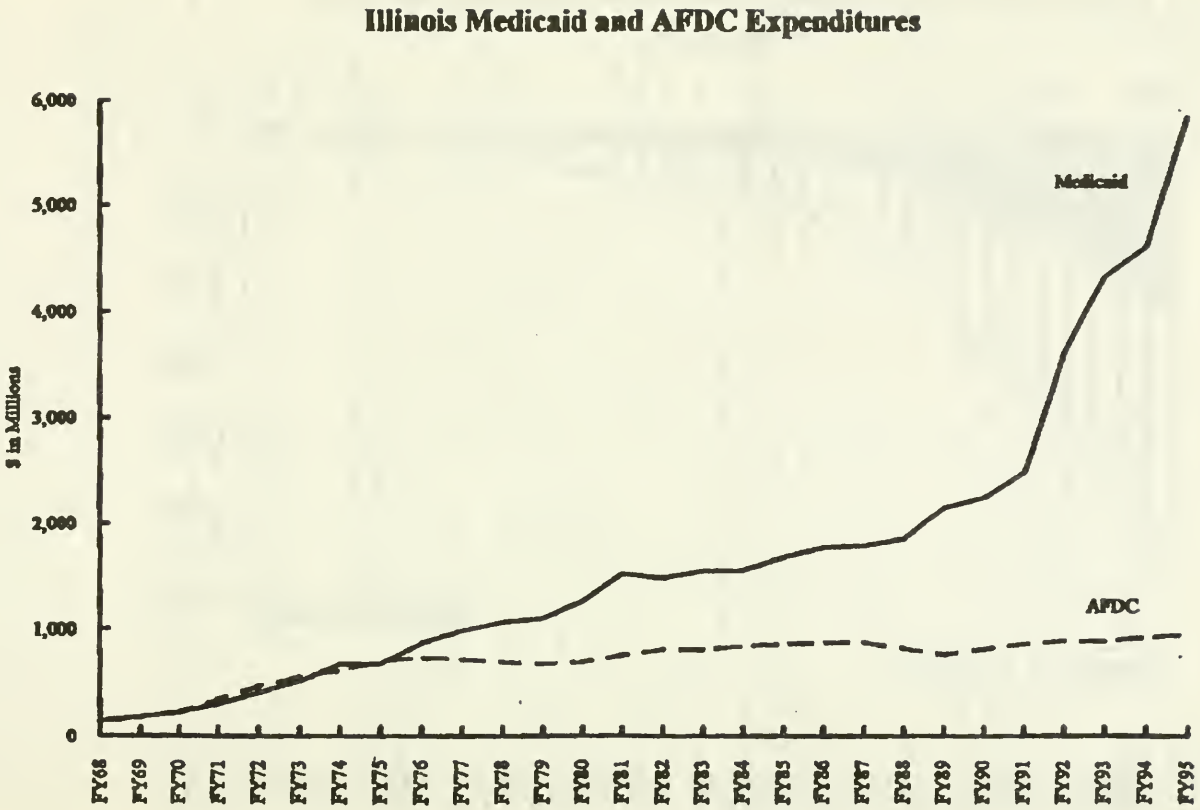
Thank you very much.

[The charts referred to follow:]

Growth in National Medicaid Spending



Source: 1966-1994: Congressional Research Service, 1995-2000 CBO projections


Illinois Medicaid and AFDC Expenditures
$ in Millions
6,000
5,000
4,000
3,000
2,000
1,000
0
Medicaid
AFDC
FY68
FY69
FY70
FY71
FY72
FY73
FY74
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Mr. BILIRAKIS. Thank you very much, Governor.

Governor Chiles, your statement, please, sir.

STATEMENT OF HON. LAWTON CHILES

Mr. CHILES. Thank you, Mr. Chairman. Good morning. I want to thank the subcommittee for inviting me to testify today. I especially want to thank you, Mr. Chairman. Florida is fortunate to have you as well as Congressman Stearns and Congressman Deutsch on this subcommittee looking out for our elderly, our disabled and our kids.

As you mentioned, I spent a few years as a member of the U.S. Senate. I have been involved in my share of the budget balancing fights and I know what it is like to try to slay the deficit dragon. I especially appreciate the tough job that lies ahead for this subcommittee as outlined in the budget resolution.

As you well know, that budget resolution directs you to save $185 billion in Medicaid programs over the next 7 years. It also says that there will be some $350 billion worth of tax cuts. We should all be mindful of the real choices that we are making as we attempt to balance the budget.

On the surface, the concept of block grants sounds fine—more flexibility and more power shifted to the States. In fact, I as Governor of Florida have been talking about flexibility for the Medicaid program since the beginning of my administration. I submitted a flexibility proposal to the Federal Government in August 1992 seeking a waiver.

I also submitted and received approval last year for the largest Medicaid waiver demonstration project in the country. That waiver when approved by the State legislature frees us from the cumbersome categorical restrictions and eligibility requirements. It will allow us to serve more people with less money and in so doing give the State and the Federal Government real savings. More importantly, it will reduce the number of uninsured in our State, keeping health care costs low for businesses, particularly small businesses with less than 50 employees.

I have watched with great interest as I learned that Congress was looking to provide Governors with more flexibility to implement their own solutions to health care problems in their States. I know that this is only the beginning of the process in beginning a new program, but I must say that I am very disturbed by what some of my friends, a few Governors from other States, have been suggesting.

I understand that some of our fellow Governors think that this new program should lock in the inefficiencies of the past program into a baseline and apply a one-size-fits-all growth rate for each State. It doesn't make a bit of sense that a State like Michigan or Wisconsin with lower population growths than States like Florida, California, and Texas should receive the same growth rate under the cap. That kind of proposal would pose a real danger to kids, the disabled, and the elderly in Florida and in the rest of the other growth States.

This is very serious business. Medicaid is a vital support link for our most vulnerable citizens. And while most think it is mainly for

poor welfare families, the fact is that two-thirds of the Medicaid funds are spent on the elderly and the disabled.

That is why Medicaid costs soar in States like Florida. The fastest growing group of Medicaid recipients in Florida are people over 85 years of age. As you know, long-term care is the costliest of all medical care. Middle-class families in America have become very familiar with Medicaid as their parents go off to the nursing home, as they expend those sort of savings that they have had during their life, and then they find themselves on the Medicaid program. And in the growth States, population increases across the board in the program, among children, among the elderly, among the disabled, and that means continued pressure on our State budgets.

Even under the most conservative scenarios, Florida's Medicaid program growth is estimated to grow between 10 and 12 percent per year over the next 7 years. These increases reflect a growing and aging population. Most of those characteristics are currently maybe unique to Florida but many States will be facing them in the future.

Florida has the largest percentage of elderly people in the Nation. The percentage of our uninsured is increasing. More than 20 percent of our nonelderly citizens have no health insurance. We have the second highest poverty rate, nearly 18 percent among the large States. And Florida is the destination not only for thousands of migrants from other countries, but also from other States, particularly during periods of recession. Many of these new arrivals require health, economic, and other financial assistance from the State.

When you factor in the certainty of recessions, the pressure on the State budget builds. Medicaid caseloads, that is the number of people in the program, typically peak about a year after the recession hits in Florida. After the last recession in the early 1990's, we saw caseload increases of more than 25 percent. No amount of State flexibility can remedy that situation.

Clearly a proposal that ignores growth factors in the individual States would be disastrous. We need to be mindful of who we are affecting with these cuts. America's neediest people, north, south, east or west, are our children living in poverty. They are also the elderly, many from middle-class homes, the disabled, and poor families. Their daily struggle would be nearly impossible without some help, the critical safety net of a Federal-State partnership.

What would a proposal to cap each State's Medicaid program at the same rate mean for the needy in our State? If you will look at this chart, in the first year of the block grants, you see that the differences would be startling. A needy person in Massachusetts would receive $4,800, two-and-a-half times as much as a needy person in Florida or Illinois, less than $2,100. A needy person in Wisconsin would receive $3,400; while in California, a needy person would receive $2,000. New York's allocation would be more than double that of Texas.

That level of inequity will never be acceptable to Florida or to any of the other growth States. Again, Florida is willing to absorb a fair share of the cuts but we can't let Florida's families be treated with less regard than families in Massachusetts or Wisconsin or

anywhere else. Dollars have to follow a path to needy people, wherever they live and when they move, the dollars should move, too.

I hope this subcommittee would not endorse a proposal to let a State use Federal Medicaid dollars for nonhealth purposes, especially when some States will be receiving far less than they will need to meet the kinds of needs of the elderly, the disabled, and kids.

You will be sending Federal funds for the Medicaid program to one State that will have the ability to divert those funds over to other programs while States like Florida and Texas and California will be cutting thousands of people off of our Medicaid program.

I think you have seen the results of this kind of gimmickry and the disproportionate share program. Shifting new responsibility to the States without a fair, equitable shifting of resources is not any kind of new federalism. It is an unwise attempt to balance the Federal budget on the backs of high growth States, and even worse, on the backs of children, the elderly, the poor, and the sick, and that is plain wrong.

That is the issue that should trouble us all, how this proposal will disproportionately hurt the elderly, the disabled, and the kids who live in growth States. I think the next chart, chart two, illustrates that point. Keep in mind these are conservative estimates. This is from the Kaiser study.

It is based on if you had flexibility and if you controlled your costs within what the inflation rate would be and what the cost rate would be, so it is taking all of those things and saying you have given us that kind of flexibility that we are demanding and we want and we have controlled our costs, then you see the States with all the flexibility that has been promised, keep spending increases per recipient to no more than the inflation rate, we would still see a dramatic reduction in the number of people served in the growth States while some States would emerge relatively untouched.

Michigan would have to reduce the number of elderly, disabled, or pregnant women by less than 4 percent. Georgia would have to cut 15 percent, or 234,000 people, off of the program. New Jersey would have to reduce enrollment by less than 4 percent. North Carolina would have to cut 20 percent off of the rolls. Wisconsin would see about a 5 percent reduction in people served. Florida would reduce 15 percent or 430,000 of our elderly, our disabled, our kids, and our pregnant women.

These are conservative estimates. I think certain of the Governors could expect to get a windfall out of this. That kind of inequity should not be allowed. We need to look carefully at how this plan impacts the people in all of the States. I know this committee does not want to endorse a proposal that says the elderly in Florida are not valued as much as the elderly in Michigan, or the children in Texas are not worth as much as the children in Wisconsin. Or tells the poor and the sick in Virginia that they won't receive the same level that the poor and the sick in Massachusetts.

Mr. BILIRAKIS. Please summarize.

Mr. CHILES. Federal support won't accompany the children, the families, the elderly, and poor and sick who move to Florida or to Arizona or to California.

Mr. BILIRAKIS. Governor, I certainly agree. I would appreciate it if you would summarize. Believe me, you will have an opportunity to expand in questioning.

Mr. CHILES. I would look forward to that, Mr. Chairman. I just wanted you to know that I didn't intend to take all of my time. You have got—I see 40 minutes up here represented on the other side and I am not going to take that much time. I want you to know that.

Mr. BILIRAKIS. Sir, there is no other side.

Mr. CHILES. Yes, sir. I hope that is right.

I think the questions that you need to ask is: Does this program treat citizens in each of our States fairly with an equitable distribution formula, or does it favor some States over others? Does it reward those States making a real commitment to reform and improved management, or does it lock in the inefficiencies of the past and turn the clock back? Does it set and maintain an appropriate, basic national standard for the care of children and others in need, or does it establish a new underclass?

Florida, I will put Florida against any State for the reforms that we have made in our program. We have cut our costs. We have cut our growth rate. We have the largest—next to the largest number of people in managed care next to our sister State of Tennessee of any State in the Nation. We are doing all of those things and we will get penalized under the House budget proposal because we lock us in at a base rate that already takes out of the inefficiencies we have and says we are going to cap you there. Any other State that is not taking those steps can start at a much higher rate. When they make the same reforms Florida has had, they will have a windfall from the outset.

You have got to be fair in the formula that you have got to set up. You have got to be fair in how you are going to distribute it. You have got to see that this burden is spread across the States in a fair and equitable way.

[The prepared statement and attachments of Governor Lawton Chiles follow:]

PREPARED STATEMENT OF LAWTON CHILES, GOVERNOR, STATE OF FLORIDA

Good Morning. I want to thank the Subcommittee for inviting me to testify today.

I especially want to thank the Chairman, Mike Bilirakis. Florida is fortunate to have Mike as well as Cliff Stearns and Peter Deutsch on this Subcommittee looking out for our elderly, disabled and kids.

I spent 18 years here as a member of the United States Senate and I have been involved in my share of budget-balancing fights. I know what it is like to try to slay the deficit dragon. And, I especially appreciate the tough job that lies ahead for this Committee as outlined by the budget resolution.

As you well know, that budget resolution directs you to save $185 billion in the Medicaid program over 7 years. It also says that there will be $350 billion worth of tax cuts. We should all be mindful of the real choices we are making as we balance the budget.

On the surface, the concept of block grants sounds fine—more flexibility and more power shifted to the states. In fact, I've been talking about flexibility for the Medicaid program since the beginning of my administration. I submitted a flexibility proposal to the federal government in August, 1992, outlining my recommendations for making the Medicaid program more state friendly.

I also submitted and received approval last year for the largest Medicaid waiver demonstration project in the country. That waiver, when approved by the state legislature, frees us from cumbersome categorical restrictions and eligibility requirements. It will allow us to serve more people with less money. And in so doing, give

the state and federal governments real savings. More importantly, it will reduce the number of uninsured in my state, keeping health care costs low for businesses, particularly small businesses with less than 50 employees.

So I watched with great interest as I learned that the Congress was looking to provide governors with more flexibility to implement their own solutions to health care problems in their states.

I know that this is only the beginning of the process in designing the new program, but I must say I am very disturbed by what some of my friends, a few governors from other states, have been suggesting.

I understand that some of my fellow governors here today think that this new program should lock-in the inefficiencies of the past program into a baseline and apply a one-size-fits-all growth rate for each state. It doesn't make a bit of sense that a state like Michigan or Wisconsin, with lower population growth than states like Florida, Texas and California, should receive the same growth rate under the cap. That kind of proposal would pose a real danger to kids, the disabled and the elderly in Florida and other growth states.

This is serious business. Medicaid is the vital life support system for our most vulnerable citizens. While most think it's mainly for poor welfare families, the fact is that two-thirds of Medicaid funds are spent on the elderly and disabled.

That is why Medicaid costs soar in states like Florida—the fastest growing group of Medicaid recipients in Florida are people over 85. And you all know that long-term care is the costliest of medical care. Middle-class families in America have become familiar with Medicaid when they seek care for parents who need home health or nursing home care.

And in the growth states, population increases across-the-board in the program—among children, the elderly and the disabled—mean continued pressure on state budgets.

Even under the most conservative scenarios, Florida's Medicaid program is estimated to grow between 10-12% per year over the next seven years. These increases reflect a growing and aging population. Some of these characteristics are currently unique to Florida but many states will be facing them in the future: Florida has the largest percentage of elderly people in the nation; The percentage of our uninsured is increasing. More than 20% of our non-elderly citizens have no health insurance; We have the second highest poverty rate (nearly 18%) among the large states; *and* Florida is a destination not only for thousands of migrants from other countries, but also from other states, particularly during periods of recessions.

Many of these new arrivals require health, economic and other financial assistance from the state. When you factor in the certainty of recessions, the pressure on state budgets builds.

Medicaid caseloads, that is the number of people on the program, typically peak about a year after a recession hits in Florida. In the year following our last recession, in the early 1990s we saw *caseload increases* of more than 25%.

No amount of state flexibility can fully remedy that situation.

Clearly, a proposal that ignores growth factors in the individual states would be disastrous.

We need to be mindful of who we are affecting with these cuts.

America's needy people—north or south, east or west—are the children living in poverty.

They are the elderly—many from middle-class homes—the disabled and poor families.

Their daily struggle would be nearly impossible without some help . . . the critical safety net of the federal/state partnership.

What would a proposal to cap each state's Medicaid program at the same rate mean for the needy in our states? If you look at this first chart [see attached] in the first year of a block grant the differences would be startling.

A needy person in Massachusetts would receive $4,800—two-and-a-half times as much as a needy person in Florida or Illinois—less than $2,100. And, a needy person in Wisconsin would receive $3,400—while a California needy person would receive $2,000. New York's per person poverty-allocation would be more than double that of Texas'.

That level of inequity will *never* be acceptable to Florida or to other growth states.

Again, Florida is willing to absorb a fair share of cuts—but I *cannot* let Florida families be treated with less regard than families in Massachusetts, Wisconsin or anywhere.

Dollars must follow a path to needy people—wherever they live. When they move, the dollars should move, too.

I hope that this subcommittee would not endorse a proposal to let a state use federal Medicaid dollars for non-health purposes—especially when some states will be

receiving far less than they'll need to meet the needs of the elderly, disabled, and kids. You'll be sending federal funds for the Medicaid program to one state that will have the ability to divert those funds over to other programs while states like Florida, Texas and California will be cutting thousands off our Medicaid program.

I think you've seen the results of that kind of gimmickry in the Disproportionate Share program.

Shifting new responsibility to the states without a fair, equitable shifting of resources is *not* any kind of "New Federalism." It is an unwise attempt to balance the federal budget on the backs of high growth states—and, even worse, on the backs of children, the elderly, the poor and the sick. That's just plain wrong.

And that is the issue that should trouble us all—how this proposal would disproportionately hurt the elderly, disabled and kids who live in growth states.

I think this next chart [see attached] illustrates that point. Keep in mind these are conservative estimates. If, and it is a very big *if*, states could, with all the flexibility that has been promised, keep spending increases per recipient to no more than the inflation rate, we'd see dramatic reductions in the number of people served for the growth states, while some states would emerge relatively untouched.

Michigan would have to reduce the number of elderly, disabled, pregnant women and kids by less than 4% but, Georgia would have to cut over 15% or 234,000 people off the program.

New Jersey would have to reduce enrollment by a little more than 4%, while North Carolina would have to cut almost 20% off the rolls.

And, Wisconsin would see about a 5% reduction in people served, while Florida's reduction would be over 15% or more than 430,000 of our elderly, disabled, kids and pregnant women.

And as I said, these are conservative estimates. I think the Governor of Wisconsin and Governor Engler (I'll let him speak for himself) expect to get a windfall out of this.

That kind of inequity should not be allowed.

We need to look carefully at how this plan impacts the people in states like Florida and other growth states. I know this Committee does not want to endorse a proposal that: says the elderly in Florida are not valued as much as the elderly in Michigan; or that says children in Texas are not worth as much as children in Wisconsin; or that tells the poor and the sick in Virginia they won't receive the same level of care as the poor and the sick in Massachusetts; or that says federal support won't accompany the children and families, the elderly, the poor and the sick who move to Florida, or other growth states.

I hope you will keep in mind three critical questions as you restructure the Medicaid program.

1. Does the program treat citizens in each of our states fairly with an equitable distribution formula, or does it favor some states over others?

2. Does the program reward those states making a real commitment to reform and improved management, or does it lock in the inefficiencies of the past and turn back the clock on reform?

3. Does the program set and maintain an appropriate, basic national standard for the care of children and others in need, or does it establish a new underclass in America?

We need to be careful not to undo much of the gains we've made. I'm proud of the fact that Florida leads the nation in reforming Medicaid—we've cut the rate of growth in half and reduced the cost through managed care of Medicaid; we've imposed stringent price level controls on providers; we've encouraged alternatives to expensive long term care; and we've continued to use conservative standards for eligibility. These approaches are creating significant savings today.

Florida already has more than 655,000 people or 40% of Medicaid eligibles enrolled in managed care. By next year we expect to have over one million of the state's 1.6 million eligibles enrolled. Only six other states have a higher percentage of their Medicaid recipients enrolled in managed care.

We also have stringent price level controls on all our providers. The majority of providers receive no price level increases at all. Physicians, home health providers, and therapists are all capped at their current levels of reimbursement.

Similarly, Florida's payment level to hospitals, nursing homes and other institutions is strictly controlled. For our hospital impatient services, we allow only the Medicare-approved rate of inflation.

We've also maintained a tight rein on eligibility. Our AFDC payment standard is only 31% of the poverty level, ranking us 38th in the nation. We provide few optional services to the standard program.

We have done much to control costs, eligibility, and benefits. And we've saved the state and federal government money while doing so.

From 1991 to 1992, Florida's average spending per recipient *actually declined* 3% while there was a nearly 8% *increase* nationally. Our cost per recipient was under $2,400 in 1993, that ranked us 44th in the nation.

But under the approach offered by some of my colleagues, we get penalized for these cost-savings efforts. Our base year for the block grant reflects the savings we've generated. States that have done *nothing* start out at a higher base. And, as they follow Florida with reforms, they'll get another windfall.

Florida stands ready to share in the cuts—and we have already gone a long way to reduce our Medicaid costs. But, I will not stand by and let other governors, who are looking to catch a windfall, speak for my state and other growth states.

If they are so intent on having the rest of us sacrifice to balance the budget, let them participate in the sacrifice, too.

If Medicaid needs to be reduced by 20 percent to meet the goals, let every state receive the same level of cut.

Now, I think the overall level of cut is too high. And I think we'll have a disagreement over that. But, if you do need to cut $185 billion out of this program you should at least do it equitably.

I have a proposal to distribute these cuts fairly. It requires sacrifice for *all* states—including the low-growth states. It's a plan that would apply the cut fairly to all states.

For years, Congress has been told by the General Accounting Office that funds in the Medicaid program are not targeted to areas of true need.

The dollars, very simply, should go where the needy live. As the Congress looks at capping the program, it should account for the differences in population growth, poverty, uninsured rates and the percentage of elderly and disabled in each state. I am not alone in sharing that view. Governor Wilson of California, Governor Symington of Arizona and others have expressed strong concerns about a block grant formula that does not take these factors into account.

The United States was founded upon the simple but unwavering belief that "all people are created equal." That basic principle is undermined—and on the verge of being abandoned—through a block grant proposal that values people differently.

Let me end by putting it simply: The debate in Congress should not be about developing a Michigan block grant, a Massachusetts block grant or a Florida block grant.

We should be talking, instead, about a true federal-state partnership for health care.

With a true federal-state partnership, a child, or a family in Florida, is worth as much as a child and a family anywhere else in the USA.

Any proposal leaving Washington must recognize that truth.

I want a program that enables me to address the particular needs and growth of Florida.

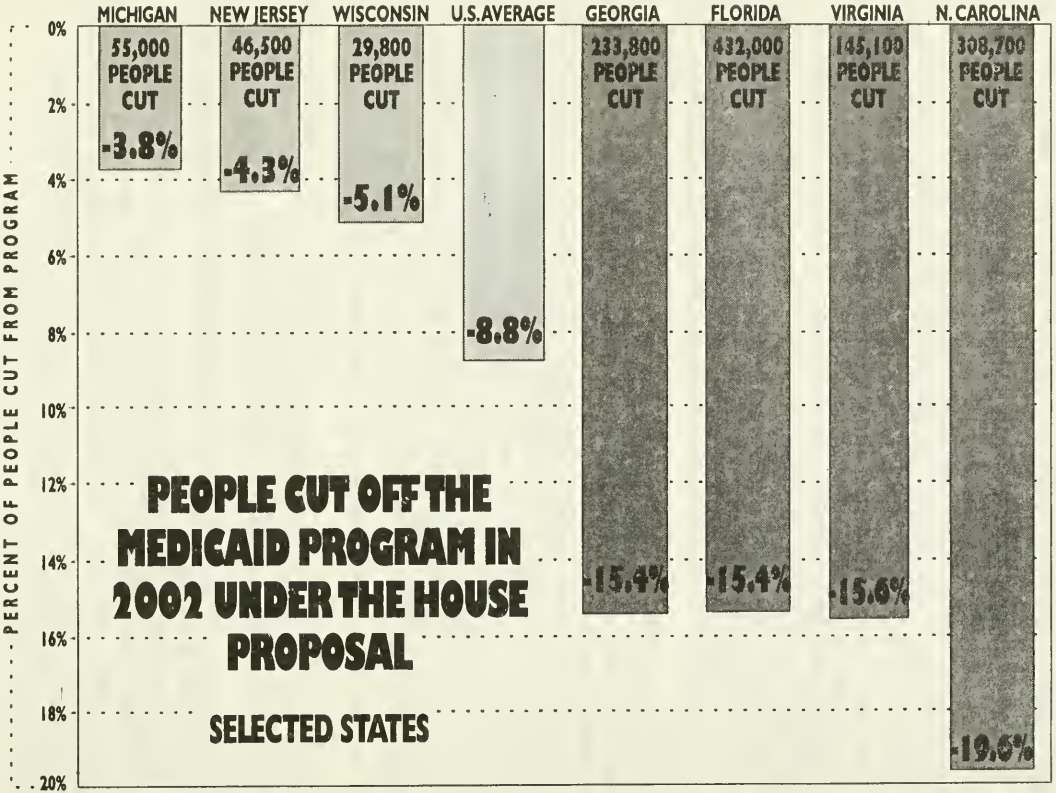
I want a program that allows me to continue the reforms that show great promise for *care*—as well as savings.

A true federal-state partnership for health care is one that has flexibility but it also recognizes the federal government's responsibility.

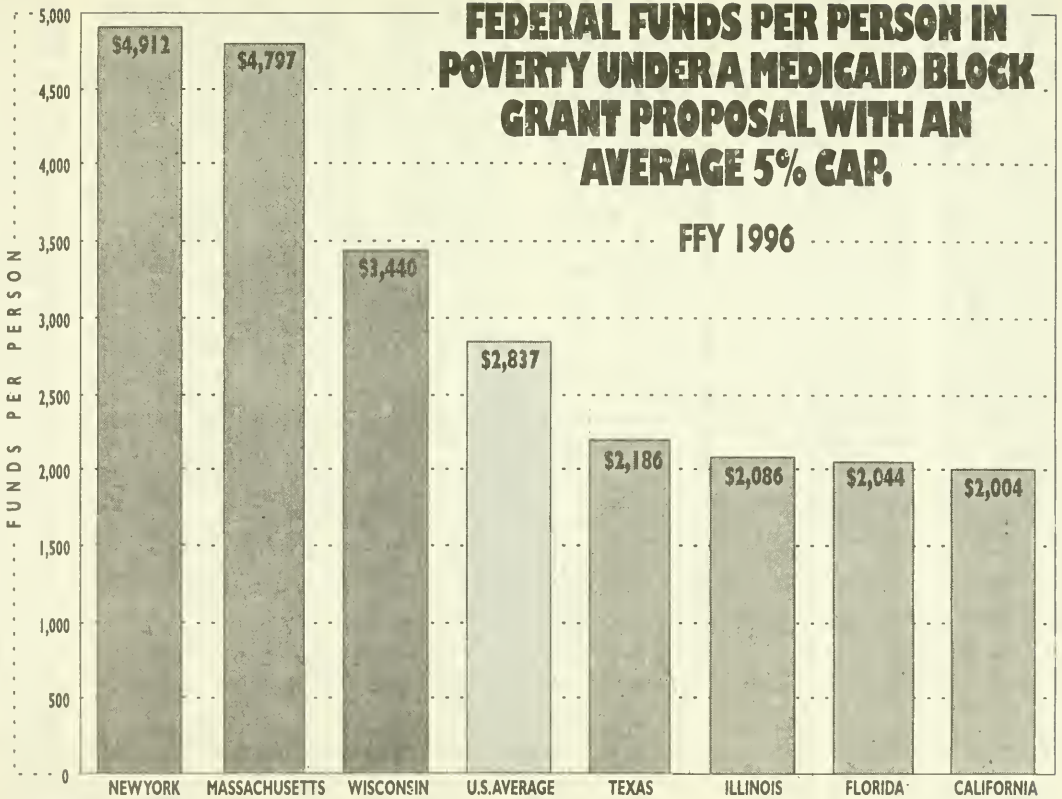
Richard Nixon championed this approach as much as Ronald Reagan. Both argued that the federal government must share the fiscal burden and ensure equal treatment of those in need.

Florida and other growth states are willing to share the load. But, we want the federal government to cooperate the way a partner should.

Thank you.



SOURCE: *Kaiser Commission on the Future of Medicaid.*



SOURCE: *Urban Institute.*

Mr. BILIRAKIS. Governor, your time is long expired, but let me just say to you and to everyone and certainly I think we have said this from the roof tops, the Budget Committee gives us dollar figures. We determine what the formulas will be and so when you refer to a budget formula or budget straight line increases 5 percent or whatever that figure is, that is nonexistent. We will determine what that is.

Mr. CHILES. I am delighted to hear that, Mr. Chairman.

Mr. BILIRAKIS. You have heard that from me many times in the past. And you have heard it again, and I assure you we are going to going to continue to work together to make sure we have equity. And with all due respect, I will shift over to Governor Sundquist now.

STATEMENT OF HON. DON SUNDQUIST

Mr. SUNDQUIST. Thank you very much, Mr. Chairman. It is a privilege for me to be here to the Subcommittee on Health and Environment and be with Mr. Waxman, Mr. Bliley, Mr. Dingell, and my former colleagues. I am glad to have a chance to talk about Tennessee's perspective on Medicaid and why I believe it must change.

As you are probably aware, on New Year's Day 1994, Tennessee embarked on a new health care reform program called TennCare. The transition to TennCare was more a necessity than anything else, since without radical change, the uncontrollable growth in the cost of Medicaid threatened the financial stability of State government and the quality of health care in the State of Tennessee.

In itself, the fiscal growth rate of the Medicaid program in Tennessee represented a significant problem as well. The program through the years has evolved as a patchwork program attempting to increasingly cover more people with more services. As a result, the number and types of different requirements on the States in the areas of eligibility, mandated services, and reimbursement have left States with very little flexibility to design and implement our own programs. The waiver process that has been developed is often so cumbersome and time consuming and is not the most efficient option to pursue innovative health care reform at the State level.

In addition, the current categorical linkages that exist for Medicaid eligibility in most areas by and large act as disincentives that actually encourage dependency on welfare. Let me illustrate. Take the case of an AFDC mother who goes to work. She is in danger of losing her Medicaid benefits for herself and her children after having worked a period of time. Oftentimes these benefits are worth more to her and her family than employment at low wages by employers who do not offer health insurance. So therefore her decision to stay on welfare and continue to receive those benefits is one that is made rather than going to work.

Another area of concern is that the current Medicaid program fails the working poor. There are many individuals who do not have access to the types of services and benefits provided to the insurer and Medicaid population. In Tennessee, we estimated prior to TennCare that number of uninsured to be over 400,000 people.

Mr. Chairman, and members of this distinguished committee, as Governor of Tennessee, I believe it is time for our Nation to no longer accept a health care program that continues to grow at an unmanageable level, offers the States little flexibility in its policies and procedures, and encourages dependency on welfare, and fails the working poor.

As I mentioned earlier, we in Tennessee moved away from this system to a health care reform program called TennCare. I will not spend time today to describe TennCare. I have attached a description of that program in my written testimony.

Rather I would encourage you to move forward with a proposal that allows States to use Medicaid funding in a manner that is consistent with the indigent health care needs of each State. Without this type of change in Federal legislation, States will increasingly have to look toward major increases in taxes each and every year. Massive health care reductions, reductions in reimbursement, or some combination of all which may or may not be in the State's best interest.

Therefore, I believe it is important to move forward with block grant legislation. However, it is also important to keep in mind that States must have the ability to design health care programs that work for them with as few strings as humanly possible.

The idea of a capped block grant to the States is a good one. However, the caps in the growth rate must be reasonable and the distribution of the funds must also be reasonable.

In addition, I think States must have the latitude and the flexibility in dealing with populations to be covered, services to be provided, and the amount of payment for those services. There should be few strings, if any, tied to these important areas as contrasted to Medicaid's multiple requirements.

It is also critical that the States' financial contribution to the program be dealt with in a manner that does not jeopardize the integrity of the indigent health care programs and yet provides for the ability of the State to be able to meet its financial requirements. Matching formulas should be eliminated and replaced by reasonable maintenance of effort requirements.

In addition, the role of the Federal Government in providing oversight must be changed. I do not believe I could responsibly come to you today and suggest completely abandoning Federal oversight. However, I do believe Federal oversight should be limited in a block grant environment.

Finally, Mr. Chairman, and members of the committee, as you continue your discussions on proposals that would change the basis of the Medicaid program, it is important that States like Tennessee who have pioneered health care reform not be penalized financially or otherwise as a result of our efforts, and I don't agree with all the testimony given by my friend and colleague but I do agree there that the States who have helped make the progress should not be given a penalty as a result of that. I would strongly propose that in whatever is ultimately developed as a Medicaid alternative that States like Tennessee have the option to maintain the section 1115 waiver that we are currently operating under for the duration of that waiver.

Mr. Chairman and members of the committee, thank you for giving me the opportunity to testify today. I believe I have a unique view on this. This is a program that was conceived by a Democrat Governor and approved by a Democrat administration.

I came to office after having served in this body so I have seen both sides of this. Despite previous efforts at health care reform, there continues to be a vicious cycle of being indigent and unable to obtain necessary medical care to maintain a health status that leads to financial improvement. There continues to be a health care system for the poor that has fragmentation, duplication, and much abuse in it. It is time to move away from this program. I believe the move to the block grant for Medicaid will allow States the necessary framework to address these complex indigent health care issues. I do appreciate, Mr. Chairman, you leaving the record open for additional days. Thank you very much.

Mr. BILIRAKIS. Thank you, Don. It is certainly a pleasure to see you here and have you here.

Governor Engler.

STATEMENT OF HON. JOHN ENGLER, GOVERNOR, STATE OF MICHIGAN

Mr. ENGLER. Thank you, Mr. Chairman. I also need to use of one Governor Chiles' first charts. The first chart I saw—you put those away. I need that first one back out because it actually helps me make a point better than any chart that I have and so I do need that one. I thank him very much for bringing that chart. I will get to that.

Mr. Chairman, I am honored to join my colleagues today to have an opportunity to give you a perspective on Medicaid from Michigan. I am delighted to be in front of a subcommittee that has three members from Michigan serving on it. So it is a committee on which our State is well represented, and I want to speak for the people of Michigan in saying we are very much impressed by efforts of the House and Senate leadership to rein in Federal spending and to balance the budget. It is long overdue and it is a goal that we support.

Runaway spending is not only breaking the Federal budget; it is placing an enormous burden on State budgets. This Congress has shown great courage in the face of intense opposition from defenders of the status quo. Every change you make is subject to attacks and distortion. For example, when the House correctly sought to give the States control over programs like school lunches, a decision I strongly support, opponents were quick to decry the decision and hold press conferences in school lunch rooms, asserting that school kids would go hungry as a result of the action of the House. Certainly, opponents of Medicaid reform will not hesitate to use similar scare tactics and in fact the second Chiles chart actually is such a tactic. We cannot allow this fog to obscure the objective that is so important.

Medicaid today is the biggest single burden on our budgets. And I don't think I am alone in saying that no State can afford it anymore. Obviously, the testimony today is consistent with that point. Certainly not in its present form. Considered a milestone when it began in the heyday of the Great Society, of 1965, Medicaid costs

are now a millstone. In Michigan, $1 of every $5 in our general fund, 20 percent, is required to fund Medicaid. And because past Congresses have saddled us with a host of mandates, these costs just keep climbing. And on top of the mandates, the Health Care Financing Administration, HCFA, keeps changing their rules and that means costs just keep climbing even higher. The bottom line: This is one very expensive program.

Now, let me reiterate. I fully support the need to rein in Federal spending. But to simply limit increases in Federal funds while doing nothing to relieve States of the burden of unfunded mandates and program micromanagement will hurt our ability to provide the poor with quality health care. I have got a chart that shows graphically just how much direction we already get from Washington. And it is quite enough, thank you very much.

This is sort of the process for making decisions, the same process that is represented by the paperwork that Governor Edgar brought today. It is so much direction in fact that the average front line worker in our State spends 80 percent of his or her time doing paperwork and only 20 percent solving the family problems that created the dependency in the first place.

The most recent GAO report shows that the current Medicaid policy is bankrupt, that it is really the sick man of the Federal budget and in need of emergency treatment. Given the budget resolutions passed by the House and Senate this year, it is clear now that the surgery is imminent.

And as I see, you have the opportunity to pursue one of two strategies, and if I could have the first chart back from Governor Chiles. One strategy would be to simply reduce Federal funding for Medicaid and keep all current rules and regulations. And this chart what I would like you to look at this, this is depicted as what would happen in 1996. It is also a depiction of what is the case in 1995. Take that chart and deduct 5 percent. That is your current spending in Medicaid. That is the fair system that today's rules and regulations yield. And that is exactly why change is needed. I mean that is today's system and the chart shows it very, very effectively. And it is a system that we have had for a number of years.

Now, the other strategy instead of saving that system would be to fundamentally change the nature of the program by turning it into a block grant. Now either strategy would accomplish the goal of reducing Federal outlays. But the only strategy is the block grant strategy that really holds any hope of helping our most vulnerable citizens and assuring that they will continue to receive health care that they need.

One thing is absolutely clear: We cannot just stay the course, that is, the course of today. And imagine if we did nothing and that at the end of the budget process decided that, yes, we do have to reduce the Federal debt and so instead of a status quo budget, we will allow a 10 percent reduction and then take those same numbers and drop them by 10 percent and say that is the program for next year and that meets our budget targets. That would simply be unacceptable.

Now, creeping micromanagement has entangled us in a briar patch of perverse incentives that are costing taxpayers dearly. For

example, a direct result of the Boren amendment in Michigan, in 1989, Michigan Medicaid costs in a nurse's facility were $35 a day. In 1994, they were up to $57 a day. We are paying a lot more money, but our patients are not getting a lot more care, and I find myself asking what is wrong with this picture. Can we do no better than this? I believe we can.

The Medicaid program, as it is now structured, will increase by at least 10 percent a year, three times faster than the State revenues that support it and considerably faster than Federal revenues as well. If current trends continued, Medicaid would grow from one-fifth of Michigan's State budget today by one-third by the year 2002. In dollars, just to give you a sense, Michigan in fiscal year 1980, total spending on Medicaid Federal and State $782 million. Fiscal year 1996, $5.8 billion. Just in the 12-year period. So the Michigan budget if we continue these trends would be strained to the breaking point by top heavy Medicaid burdens.

So I applaud this committee for considering reforms that will change the financing and structure of Medicaid so that the States can take full responsibility for and control of the program. Speaking for Michigan, I welcome the opportunity to design Medicaid to reflect the values and priorities in our State and to provide for our most vulnerable citizens who need health care services. However, I am aware that some of the proposals in Congress, aided and abetted by the status quo lobby forces, would continue to tie our hands and attempt to micromanage Medicaid from inside Washington. And I think this would be a serious mistake for at least two reasons.

First, any provisions that require "set-asides" for specific populations are unnecessary. No child, no elderly person, no individual with disabilities is going to be abandoned when Michigan takes control of its Medicaid program.

Second, any financing mechanism that continues the Federal matching formula is not acceptable. I want to repeat that. Not acceptable. The matching rate approach will only keep that current system up there hobbling along and burden State and Federal budgets with a host of perverse incentives. I believe we can do better and the type of block grant I am calling for would fix Medicaid and reform the system.

A Medicaid block grant with no strings attached would give States flexibility to be innovative while maintaining necessary services. Flexibility, coupled with growth rates projected in the budget resolutions, create a win-win situation for both beneficiaries and taxpayers. Another benefit of flexibility will be the acceleration of reforms because today's cumbersome waiver process would be eliminated.

Finally, the committee knows and I know that one of the biggest barriers to getting off welfare is access to health care. In March 1994, I submitted a waiver request for HCFA that would guarantee access to health care for anyone who leaves welfare for a job. And a year later, we are still waiting for an answer. With block grants in place, we already would have implemented the proposal, and more people would now be independent.

And I think the only condition that this committee ought to insist on is that a block grant to the States require States to use the

money to finance health care for low-income citizens. I think that is completely rational and reasonable. Then I invite Congress to judge us by the one criterion that really counts, performance. I think Michigan already has a very strong track record. We have a Healthy Kids initiative where we have actually expanded Medicaid coverage, and today Medicaid provides one of every four children in Michigan with health care coverage.

Even with today's constraints, our managed care system is a national leader that covers 82 percent of our Medicaid recipients. So I am proud of our achievements but I am very excited about the prospect to do so much more with the reforms that are anticipated. Thank you very much.

Mr. BILIRAKIS. Thank you, sir.

Governor Leavitt.

STATEMENT OF HON. MIKE LEAVITT

Mr. LEAVITT. Mr. Chairman, members of the committee, I am delighted to be here, along with my colleagues, to address what I suspect are two basic issues. The first is the best strategy for Medicaid and the second is how can we assure that we do not end up limiting Federal expenditures simply transferring a burden to the States.

Utah, like my colleagues, has been involved in the Medicaid system for some time. It serves one out of eight of our citizens. I would like today to challenge the thought that moving to a block grant would automatically result in our citizens being removed from health care rolls. In Utah, we have been a leader in setting forward efficient and able Medicaid systems that leads us to have been, I think, one of the best managed States in the country as put forward by Financial World magazine. Since 1981, we have been employing a lot of the competitive purchasing techniques in the marketplace. We have been since 1982 dealing with HMO products in our Medicaid system.

In 1993, when I became Governor, we instituted along with my legislative colleagues on a nonpartisan initiative, a blueprint, a Healthprint, we call it, a blueprint for market based reform in health care; a major component of that, of which there was an objective to provide access to affordable health care to all of our citizens by the year 2000. And we are three steps into that process and we are successfully adding to the rolls each year thousands of Utahns who otherwise would not have health care.

Now, a significant component of that was an 1115 waiver that would have allowed us to expand Medicaid by 20 percent without adding to the Federal expenditures or our State expenditures. We did that, of course, by using a lot of techniques that are employed elsewhere in the health care system, but because of method mandates, because of court decisions, and because of regulations, our hands have been tied and we simply have not been able to implement those things and we need that flexibility.

The Medicaid program has evolved into a myriad of subprograms, each request their individual subset and individual rules. The administrative flexibility and simplification have given way to unsurpassed complexity. All of this is contrary to the dramatic changes that are taking place in the health industry. The waiver

process simply has failed. It puts forward artificial rules and conditions and it has no bearing on what is going on in the marketplace.

While there are many, many examples of how Federal administration of Medicaid has failed to meet the needs of States and its citizens and this country, I would like to just point out a few. First, there is the outdated Boren amendment. It ties States to a reimbursement system of obsolete cost-based methodologies rather than using a competitive market trend that has evolved in the markets.

Next, let me talk about the so-called "optional" services that each State can supposedly add or subtract to its benefit package to stay within budgetary constraints. Unfortunately, Federal law and regulation have restricted States from being able to remove those optional services from so many subpopulations that by the time all those protected eligibility groups have been eliminated there is very little cost savings involved.

Now, we have some difficult choices in this country to make with respect to this matter. The current system simply prohibits States from being able to face those difficult decisions. An example. Again, I draw from our State. Currently in our State, a Medicaid recipient receives 130 percent in terms of the richness of the benefit package that a person working in the private sector would receive in our State. Now we went through a fairly elaborate process of receiving input from our citizens, our low-income groups, and made a decision that we were prepared to reduce those benefits from 137 percent down to 118 percent of what the average worker would receive. But we were told that wasn't consistent with the philosophy of the national government and therefore we shouldn't be able to do that.

Now, I would like to emphasize that our purpose in doing this wasn't simply to reduce the budget. Our purpose in doing this was to give more people coverage. Rather than have people in our State without basic health care, our desire was to take the savings and to spread it over more people. Now that may not be the philosophy of the national government, but strongly in Utah we would rather have all of our citizens to have basic health care than have a few have 30 percent more than the people who are out earning it in the marketplace. Now that makes sense to us and we need that kind of flexibility to make our system work, particularly in the new environment where we are facing financial reality.

Another example of Federal law and regulation that has so tightly limited our capacity is the use of copayments and other forms of financial responsibility within the Medicaid population. Reasonable cost sharing requirements must be injected into this system or any system of health care reform if we are going to gain control of the program and assure its finished availability to all of our citizens.

In the administrative area, the explicit and expensive requirements that have been imposed by Federal law and regulation on the operation of Medicaid agencies have inhibited the design of a basic program to transfer greater responsibility to private health plans where they can be more cost effective in bearing responsibilities.

There is simply in the future, for example, no need for States to maintain the expensive and complex Medicaid management infor-

mation system. In fact, in the State of Utah, we are presently operating on a trial basis a single comprehensive medical billing system that electronically processes claims from all provider types.

UHIN, as we refer to it, the Utah Health Information Network, collects claims on behalf of all public and private insuring entities in Utah. UHIN is a nonprofit organization that was formed voluntarily to address the growing concern about duplicative administrative expenses incurred by multiple insurers.

UHIN receives claims either manually or electronically, processes them for payment against the requirements that each insurer provides, and saves an enormous amount of money in time and speed in being able to process these claims. UHIN is just one example of how States are moving aggressively to implement real health care reform that will stand the test of time and the marketplace. This is the time for action. These are the types of things we have to be able to do if we are going to solve this problem within the context of our budget.

As Congress looks forward to limiting the amount of Federal funds available for Medicaid, it is vital that States be given the tools necessary to craft a program that is not only efficient but that continues to provide at-risk populations good quality health care. In my opinion, the most important tools we could have would be flexibility and the ability to do things that simply make sense, and currently that ability is prohibited to us by a morass of Federal regulations, a latticework of tools and overlapping eligibility requirements. We can do a better job of this given the opportunity. Thank you, Mr. Chairman.

[The prepared statement of Governor Michael O. Leavitt follows:]

PREPARED STATEMENT OF MICHAEL O. LEAVITT, GOVERNOR, STATE OF UTAH

It is a privilege for me to come before this distinguished body to address two very important questions pertaining to your Medicaid deliberations. First, what is the best strategy for maximizing Medicaid's critical role in providing access to health care? Second, how do we slow the rate of growth in Medicaid expenditures without simply transferring this unsustainable liability to the states?

States have been charged with the primary responsibility to administer Medicaid since its inception in 1965. During the last thirty years, we have moved responsibly to look for ways to achieve both program and administrative cost savings, while assuring delivery of quality health care. While each state has met with varying degrees of success in achieving this goal, the evidence is quite clear that taken as a whole, the states have done a good job of serving the country's poor, unborn, disabled, aged, blind and medically at-risk citizens. This has been done in the face of heavy federal regulation and federal restrictions that have severely hampered state efforts.

In Utah specifically, Medicaid serves 1 out of every 8 Utahns each year. The philosophy of the State has been to foster market place competition and individual recipient financial responsibility to the extent permitted by federal law. This has allowed us to achieve one of the most efficient and actuarially sound Medicaid systems in the country. In fact, sound management of Medicaid has contributed in large measure to the State being consistently selected as one of America's best managed states by Financial World. Utah has employed competitive purchasing of major Medicaid services since 1981. We first included HMO products in the Medicaid program in 1982. Along this vein, the State long ago abandoned inflationary cost based reimbursement systems except where still required by present Medicaid federal law.

Shortly after taking office in 1993, I joined with my Utah legislative colleagues in a non-partisan initiative that would span 8 years of comprehensive, incremental health care reform that would ultimately make available affordable health care to all Utahns by the year 2000. This bold yet down to earth strategy is set forth in a document titled *Healthprint—A Blueprint for Market Based Reform in Utah*. A major component of *Healthprint* is expansion of Medicaid to more Utahns living at

or near poverty using no more federal dollars than would actuarially have been spent under the traditional Medicaid program. Under the current system, the Medicaid piece of *Healthprint* would take the form of an 1115 Waiver.

Unfortunately, as a new governor and as a new student navigating the complex Medicaid federal approval processes, I have discovered that this country's governors do not have the authority needed to reinvent how this vital health care program can best meet the needs of its citizenry with the limited federal and state dollars that will be available in the future. Increasingly, federal mandates, court decisions and regulations issued by federal bureaucrats have tied the states' hands when it comes to tailoring a Medicaid program that fits within the budgetary and health care environments of the individual states.

The Medicaid program has evolved into a myriad of sub-programs each with its own set of individual entitlement rules. Administrative flexibility and simplicity has given way to unsurpassed administrative complexity and insensitivity to serving the public efficiently. In addition, federal administration of the Medicaid program through its various regional offices is not proceeding quickly enough to recognize the dramatic changes occurring in our health care markets. As a consequence, states with aggressive health reform efforts are stymied by out-of-date federal regulations and waiver application processes that not only fail to respond to the opportunities presenting themselves to states today, but establish artificial rules and conditions for granting waivers that have absolutely no bearing on the realities of the market place.

While there are many, many examples of how federal administration of Medicaid has failed to meet the needs of the states, its citizens and this country, I would like to recap just a few. First, we have the outdated Boren requirements that tie state reimbursement systems to obsolete cost-based methodologies rather than the competitive market trends evolving so rapidly in most of our markets. This will continue to cost the states and the federal government billions of dollars each year.

Next, we have the so called list of "optional" services that each state can supposedly add or subtract from its benefit package to stay within budgetary constraints. Unfortunately, federal law and regulation have restricted states from removing optional services from so many special sub-populations of Medicaid, that by the time all these protected eligibility groups are eliminated there is very little cost savings left to realize.

The current system prohibits states willing to make hard choices. An example. Currently, a Medicaid recipient has benefits that are 130% of the average worker in the private sector in our state. After expensive deliberation and discussion with low income advocates, we decided that in Utah we would rather have everybody have basic health care than fewer have the best health plan in the state. We proposed to reduce the benefit level from 130% of the average private sector plan to approximately 118%, using the savings to provide coverage to people, who currently have no coverage. What we believe to be a common sense decision, was not allowed under the existing system. There may be those of you who still disagree with our decision, but if we are going to meet our objective of providing success to basic quality health care to all Utahns, we need the ability to make those hard decisions.

Another example, federal law and regulation has so tightly limited the use of copayments and other forms of financial responsibility within the Medicaid population that any strategies to save funds by sensitizing these participants to the consequences of health care utilization decisions is lost. Reasonable cost sharing requirements must be injected into the purchase of health care by a significant part of the Medicaid population, particularly adults, if we hope to gain control of this program and assure its continued availability to future generations.

In the administrative area, the explicit and expensive requirements imposed by federal law and regulation on operation of state Medicaid agencies inhibits redesign of the basic program to transfer greater responsibility to private health plans where they can be more cost-efficiently borne, and the basic responsibilities of states redefined around rate negotiation, health plan enrollment, quality of care monitoring and reporting, and health data collection and analysis.

There will shortly be no need for states to maintain expensive, complex Medicaid Management Information Systems. In fact, the State of Utah is presently operating on a trial basis a single, comprehensive medical billing system that electronically processes claims from all provider types. UHIN, the Utah Health Information Network, collects claims on behalf of all public and private insuring entities in Utah. UHIN is a non-profit organization that was formed voluntarily to address the growing concern around duplicate administrative expenses incurred by multiple insurers. UHIN receives claims either manually or electronically, processes them for payment against the requirements of each liable insurer, handles automatically the coordination of benefits where more than one insurer is involved, applies limitations and

other edits against the services received, and directs a payment remittance statement back to the provider advising of the action taken on the claim, and the parties from whom payment will be received. All organizations that came together to form UHIN committed in the articles of incorporation to return all administrative savings that are derived from this public/private venture to the consumer.

UHIN is just one example of how the states are moving aggressively to implement real health care reform that will stand the test of time. The time for action is now, and the place for this action is the individual states.

As Congress looks toward limiting the federal funds available to the Medicaid program, it is vital the states be given the tools necessary to craft a program that is not only efficient, but which continues to provide at-risk populations good quality medical care. In my opinion, the most important tool the states must have to accomplish this is flexibility.

Franklin D. Roosevelt said "The future lies with those wise political leaders who realize that the great public is interested more in government than in politics". As the nation's governors, each of us has the first line responsibility to understand our communities needs and the values based on which those needs must be met. I hope we have the courage and the wisdom to give states the needed flex to make critical decisions relative to managing Medicaid within a mutually acceptable funding agreement. This is the only path I see that will enable us to both balance the federal budget and preserve this important program.

Again, it has been my pleasure and privilege to speak to you today, and at this time I would be very happy to speak to any specific questions or concerns you may have.

Mr. BILIRAKIS. Thank you so much, Governor.

Well, gentlemen, I appreciate so very much your testimony. We are going to go into the questioning now on the part of the members of the committee.

I am going to try to hold to that 5-minute rule as closely as possible. I don't think we are going to have time for a second round, so I would rather no one comment on that. I will kick it off.

I believe that the testimony of our distinguished panel of Governors demonstrates that we all agree that the Medicaid program has a disastrous fiscal effect on both the Federal budget deficit and the budget of all the States. The Medicaid mandates that are initiated in this committee have been the single principal cause, or it has certainly been a principal cause of State budget pressures and Federal deficits during the past decade.

I am sure all of us, or at least most of the us have heard horror stories from all of our States regarding many of these mandates. I guess the puzzling question is how did this happen within yearly budget reconciliation bills whose sole and exclusive purpose was budget reduction?

Before Governor Chiles came in, I held up the Florida 1115 application, Governor, which as I indicated, is printed on both sides of each sheet and it does not include the accompanying documentation, which I am sure the Governor can better tell us is voluminous, and Governor Edgar has referred to the great big piles on top of his desk.

So we go on about how did Medicaid expansions become the single largest unfunded mandates on the States? Let me try to show you how by turning to this handout. We passed this out earlier, I trust all of you have it.

[The charts referred to follow:]

CBO OBRA 1989 Medicaid Mandates

Estimates vs. Actual Florida Expenditures FY1991

(in $millions)

	CBO Scoring for All States	Florida Federal Expenditures
Mandatory Coverage of Pregnant Women	$270	$31
EPSDT	$25	$63
Payment for Federally Qualified Health Centers	$15	$8
Payment for Obstetrical and Pediatric Services	$11	$4
Total	***$321***	***$106***

Florida represents 3.8% of all Federal Medicaid expenditures.

CBO OBRA 1989 Medicaid Estimates
(in $millions)

CBO Estimate	Projected Estimate Based on Florida Experiences
$321	$2,868

888% off!

Florida represents 3.8% of all Federal Medicaid expenditures.

Cost of OBRA 1989 Mandates to the States

State Share According to CBO Estimate for FY 1991	Projected Estimated State Share Based on Florida Experience
$242 Million	$2.164 Billion

g:obra89.cht

Mr. BILIRAKIS. This chart lists the official Congressional budget estimates of the four major mandates that remain passed in OBRA 1989. These include mandatory coverage of pregnant women and children, up to 133 percent of poverty line. Also mandatory coverage of early periodic screening and diagnostic treatment services, which we call EPSDT, in addition to enhanced payment for federally qualified health centers and enhanced payments for obstetrical and pediatric services.

I don't think it is necessary to point it out, but these are additional new plan dates as a result of OBRA 1989. In addition, all of the benefits covered under Medicaid previous to that.

In the first chart, the first column is the official CBO estimate, totals out to $321 billion. Let me repeat for all States, this is the official CBO estimate for all States for these benefits, for these four benefits, these four new benefits for fiscal year 1991.

The second column is the full Florida expenditures provided by Mr. Gary Clark who is the Florida Medicaid Director. Florida represents only 3.8 percent of all Federal expenditures on this program.

Let's compare the totals for fiscal year 1991; CBO calculated that the total Federal expenditure for these four mandates would be $321 million in 1991. Unbelievably, Florida's total alone was a staggering, as you can see, $106 million.

Let's look at the EPSDT line. Incredibly, CBO estimated that the total Federal expenditure would be $25 million for all 50 States. While Florida actually spent—now mind you, this is just the Federal share of what Florida spent for that additional program, $63 million, or more than double the CBO estimate in 1991. But I calculated the Federal portion added to this $63 million is $47 million on the basis of 57 percent, 43 percent break down.

I went all the way through. The mandatory coverage of pregnant women, Florida taxpayer dollars would be $24 million added to the $31 million.

The payment for federally qualified health centers would be $6 million added to the $8 million, and the $3 million added to the $4 million of the bottom payment for obstetrical and pediatric services, meaning an additional $80 million that came out of Florida's coffers, out of the Florida budget in addition to the $106 million, when, in fact, the estimate, CBO-scoring, as far as Federal dollars was concerned, was $321 million.

Let's see now, the second chart projects Federal Medicaid expenditures using Florida's actual experience. We come up with a figure of approximately $2.86 billion.

Therefore, while CBO projected Federal expenditures, the Federal share of $321 million, actual expenditures were closer to $2.8 billion, an error of approximately 888 percent.

This example I think shows how Medicaid dramatically contributed to the growth of the Federal deficit when members enacted Medicaid law based on totally erroneous estimates. But this is only, I think, half the story. These unfunded Federal mandates were also a devastating fiscal blow to the States, and all of you have referred to that.

Why? Well, because Medicaid is a matching program with the States picking up 43 percent of the tab, and, of course, I have gone into that.

So let's look at chart No. 3, which shows somehow CBOs misstatements led to State budgetary havoc. While CBO projected $242 million in State expenditures on the basis of that $321 million estimate, the actual expenditures were in the range of $2.1 billion.

Because all States must balance their budget, either the State taxpayer pays the piper, or funds had to be taken from education and other social programs to pay for Medicaid. Not surprisingly the National Governors Association passed a resolution in 1991, signed by all Governors, I referred to that in my opening statement, including then Governor Clinton, asking for repeal delay or modification of all of these unfunded mandates.

I am not sure how much time I have left, but I would like to give all the Governors a chance to comment on the budgetary folly, if, in fact, they think this is a folly of this program. Please tell us what these Federal unfunded mandates did to your budgets?

Whoever would like to start it off.

Mr. EDGAR. I agree. In fact, it is not to say these aren't worthwhile programs, but there are a lot of other very worthwhile programs in Illinois we couldn't fund, like more early childhood education, programs in education, mental health, because we didn't have a choice. We were mandated to do these. We weren't given the ability to really set the priorities, and that is a frustration I think every Governor feels when he is told by the Federal Government—I might say in our State, we had only a 50 percent match, so it hits us especially hard when we are mandated to do something in Medicaid, it just means less dollars for other programs.

Mr. CHILES. Mr. Chairman, I think there would be no disagreement that all Governors want flexibility. All of us certainly think the program is badly flawed now; that it does require us to continue to add tremendous sums of our money.

I think with different concerns, perhaps, to the question is, if you are going to change it, are you going to fix it better for us or are you going to make it worse for us as you change it? That is the fear that some of us have.

Mr. BILIRAKIS. Governor Sundquist, I, for one, have an awful lot of confidence that your heart is as big, as caring as any heart on this committee.

And I honestly feel that if we give you the resources—and I grant it, maybe they are never adequate—if you will, if we give you the resources based on fairness and justice, that the State of Florida with your leadership can do the job. And this is why I support the block grant concept, with no strings attached. With the exception of the one that all of you mentioned, and that is that parameter that money has to be used for health care reform.

Mr. SUNDQUIST. Thank you, Mr. Chairman.

You are absolutely right on the cost of mandates, they are terribly expensive. As we looked at these charts earlier, the emphasis on it by some was how much money will it cost States when, in fact, if you will free us up, we can save you money, and we need to talk about cost savings as a result of reduction of mandates.

I believe Governors can be trusted. Our necks are on the line, and I appreciate the confidence that you have in us. And, for instance, we can't charge under our agreement with HCFA, we can't charge anything for emergency room visits.

Well, how expensive are emergency room visits? And when people get treated in the emergency room, that is the most expensive form of treatment. A small charge will move those people in the right direction and will save money and allow us to reinvest those same dollars another way.

We are close to 94 percent of the people in Tennessee covered under insurance, at the present time. We saved in the first year of TennCare, we saved about $900 million for State and Federal Government. There are dramatic savings that can be made, if you will get us out from underneath these onerous mandates and requirements that are being dictated out of Washington, as opposed to what we in Tennessee request to manage with, and we can spend your dollars, our dollars a lot better. I think so.

Mr. ENGLER. There is very little to add. We showed that between 1984 and 1993, there was something like 35 major expansions in Medicaid that were mandated by Congress, and you have certainly done an effective job of just detailing one of those. So the totals I think, if we include Boren, we end up over $300 million in total mandated increased costs and a good deal of that is paid by the Federal Government. And the rest of it is paid by the State. Your display is a good one.

Mr. BILIRAKIS. Governor, anything to add to that?

Mr. LEAVITT. No, our experience is consistent.

Mr. BILIRAKIS. My time is long expired.

In any case, Mr. Waxman.

Mr. WAXMAN. Thank you, Mr. Chairman.

I want to direct this to Governor Edgar.

The Republican Budget Resolution, which you and your Republican colleagues are supporting, would reduce Federal spending on Medicaid by $187 billion over 7 years. Now, the Kaiser Commission on the Future of Medicaid, issued an analysis of the impact of these cuts on your State and on other States. The analysis was done for the commission by two economists, John Hollahan and David Liska, of the Urban Institute. What they found was that over the next 7 years, Illinois would lose $6.2 billion in Federal Medicaid funds, a cut of 18.7 percent.

In the year 2002 alone, Illinois would lose $1.8 billion in Federal funds, a 1-year reduction of 30 percent. The researchers looked at the impact of these cuts on beneficiaries.

Now, they made certain assumptions, and I think you probably agree with these assumptions. Your State would control spending by enrolling beneficiaries in managed care. You would reduce covered services and you would cut provider reimbursement rates only after you had made these changes. The researchers thought you would then cut back on enrollment or the eligibility for people to be on the program.

What the researchers concluded was that despite aggressive use of managed care and reductions in provider payments in covered services, States would still have to cut back on coverage. And they estimated that in the year 2002 alone, Illinois would have to elimi-

nate coverage for more than 82,000 people; 59,000 would be mothers and children; 7,000 would be elderly; 17,000 would be disabled. In short, they don't think that you can deal with these cuts in Federal funds without stripping people in your State of health care coverage.

Now, their analysis is very conservative. It doesn't even take into account the special problem your State now faces, and that is the, roughly, $1 billion you already owe hospitals and other providers in Illinois for services they delivered in the past.

It is my understanding that this debt used to be $1.3 billion, but your State budget, recently adopted by the legislature in Illinois, had a cut of $200 million from welfare programs for disabled people, abused and neglected children, dental care for the poor in order to help pay down this debt to the hospitals that you owed under Medicaid.

About $40 million of these saving come from reducing payments to blind and disabled adults from $154 to $60 per month.

Now according to a recent article in Crane Chicago Business, this same budget also reduced payments to hospitals with heavy Medicaid patient loads by 85 percent, from $400 million to $60 million per year. The biggest losers are the University of Chicago, Mount Sinai, Children's Memorial, Northwestern Memorial and Rush Presbyterian Hospitals.

In short, it looks like your State is already robbing Peter to pay back Paul even before the Republican budget cuts start to take away large amounts of Medicaid dollars from Illinois.

Here is my question: I want to know what your plan is going to be? How are you going to deal with the loss of $6.2 billion in Federal funds in the next 7 years?

How are you going to exercise all the flexibility you are asking for? How much of your money in State dollars could you continue to spend on health and long-term care?

Which provider rates are you going to cut and how much? Which services are you going to stop covering?

Which beneficiaries are you going to end coverage for. The elderly, disabled, mothers and children? Under the block grant you are seeking, we will probably repeal the Federal rules that States have to pay providers on a timely basis for the services they deliver.

Are you going to pay back the Illinois hospitals the $1 billion you still owe them, or do you intend to use your flexibility to withhold payments from providers in the future as well?

Mr. EDGAR. How much time do I have to reply?

Mr. BILIRAKIS. About 3 minutes.

Mr. WHITFIELD. Mr. Chairman, I think we should give him more than 5 minutes to respond.

Mr. EDGAR. Let me, first of all——

Mr. WAXMAN. My question is illustrative of the kind of problems your State is going to have, but other States are going to have similar ones. Tell us how you are going to do it.

Mr. EDGAR. First, I would like to say, you keep talking about cut? My understanding is no one has talked about cutting Federal match or assistance. We are talking about trying to limit the explosive growth, and that is something we are trying to find at the State level. So we don't view it as a cut.

We view it as trying to limit growth, and I think everybody recognized we need to find a way to limit growth of the Medicaid cost at the State level.

Second, let me say we do have problems with Medicaid today in Illinois. Two reasons: One of the mandates that Congress passed on us, I pointed out in my testimony this last year alone, $460 million of our increased costs in Medicaid came from the mandates that passed here during the late 1980's and early 1990's, and that has been a real frustration for us in Illinois and throughout the Nation, I think every Governor, the mandates that we have been forced upon and had to come up with the cost.

Second, one of the great frustrations we now have is we think we have a way to deal with this problem. Managed care, it is not a unique concept. Many other States have been granted waivers.

But we get a delay, and delay, and delay from HCFA. As long as we have those kinds of bureaucratic hurdles to overcome, we can't deal with the problem. So I firmly believe that if we can get the waiver, we can begin to deal with the problems we now face, but also we are not saddled with more and more mandates from the Federal Government.

Now, I am not familiar with the study that you mentioned. I will say, though, that as we can tell right here from what CBO said in their study, you can't always depend on those studies being that accurate.

We believe in Illinois, if we are given the flexibility that is being talked about as far as letting us determine how to deal with the poor in our State, that we can do it in a much better and more efficient manner than what is being mandated from Washington and the types of increases that has been talked about, and the future under the Republican proposal, we believe with the flexibility, we can deal with the problem.

But we can't if you continue to give us more mandates, if we continue to have the Federal Government say no when we are trying to innovate and take programs that other States have been able to put into effect and have worked very well.

Mr. WAXMAN. I appreciate that answer, Governor.

What we are talking about in the proposal is an effect on the Federal dollars, because we are going to take all the Federal dollars, whatever they are going to be, and apportion them out in block grant funds to each State, and that is one point. The other point is the flexibility.

You already have flexibility without a set limit of the Federal dollars, which is the existing Medicaid program. But the point I want to draw your attention to, and others as well, Governor Chiles pointed out we have States like Florida, California, and Texas which are growing very fast. I am pleased to hear the chairman wants to recognize that.

Governor Sundquist mentioned that he thinks when we build in the base, we ought to recognize that they have already made efficiencies in Tennessee. Well, they have. But they have got a 6.6 percent growth increase for TennCare, and they are going to have at best a 4 percent increase in Federal dollars in the future to pay for it. But the point I want to make is that Tennessee has been effi-

cient but they are also covering a lot of people that other States aren't.

Now, my taxpayers from California are going to say, why should we pay taxes when we are a high-growth State, to help pay for a lot of people who aren't going to be covered in California but will be covered in Tennessee. This is the problem we are going to have in this Medicaid program.

Governor Sundquist isn't here, but what he has asked for, is to have his cake and eat it, too, and I don't blame anybody for asking. But the Federal Government is going to have a real problem meeting all the desires of all the Governors if we are going to have a pie that is going to be reduced in its growth and then distributed with some presumed equity. And then it seems to me, the job of the Governors, with all your flexibility and despite all your good intentions, will be to cut people out of the program.

Mr. BILIRAKIS. The gentleman's time has expired.

Mr. WAXMAN. I would ask one question, and maybe we can get it in really quickly, if you all believe we ought to cover low-income elderly for nursing homes and women and kids below the poverty line, or up to 133 percent of the poverty line and——

Mr. BILIRAKIS. The gentleman's time has expired.

Mr. WAXMAN. Are you willing to let us put in that they ought to be covered and give you all the flexibility in the world to do it?

Mr. BILIRAKIS. The gentleman's time has expired.

Mr. Bliley.

Mr. WAXMAN. Could we get an answer, maybe a quick one?

Mr. BILIRAKIS. You have gone about 12 minutes.

In the process, probably responding to the others, they could respond.

Mr. WAXMAN. I think it could be a yes or no answer, real quickly.

Mr. BILIRAKIS. Mr. Bliley.

Mr. BLILEY. Thank you, Mr. Chairman.

You say that incremental, Governor Edgar, you say that incremental reform has been tried and it is simply not enough. Would you explain what do you think were the reasons behind the failure of past attempts to get control of the Medicaid program?

Mr. EDGAR. Well, I think there has been a resistance on the part of the HCFA on really giving the States the flexibility, and part of it has also been from Federal law. You know every time you go into a waiver, you might eventually get the waiver, we hope at some point we will get the waiver, but it is going to be probably far different from what we ask for. You negotiate day in and day out with the Federal bureaucrats, and they have their job to do, but I don't think they are as responsive and sensitive to what the needs in a State are as elected officials of the people who are in that State.

Again, Mr. Waxman's question about what are we going to do? To imply that States don't have more concern or sympathy to the people out there and Congress might have more, I just disagree.

We are all elected by the same people. We are all held responsible, and I think in the case of Medicaid, those of us at the State level, particularly elected officials, we are held more responsible than the bureaucrats are in Washington. So again, the experience we have had has been any time you come in for a waiver, you never get what you ask for. It gets watered down considerably. And

as a result, you can't really put in the sweeping reforms that you need.

And I mentioned everybody here I think has gone through a long, drawn out experience trying to get waivers, and what we would like to be able to do is put those plans into place quickly and begin to save dollars and provide better service to the people that we are trying to help. And those are the ones I think everyone here wants to help but, unfortunately, we can't do the job we would like to do under the current system.

Mr. LEAVITT. Mr. Bliley, can I make a comment on that?

There are times you do get what you ask for and it doesn't work, but in the doing, you discover something that will.

Well, in a normal circumstance, you are able to say, let's change this. But you have to come to Washington now and get a new waiver and wait another 15 months. You just need the capacity to find out what works through sometimes trial and error. But that is life and it is real and we can fix it, given a chance to do that.

Mr. BLILEY. Thank you, Governor.

Governor Edgar, you suggested in your testimony that failure to reform Medicaid would eventually deprive States of their ability to meet the health needs of poor children and other disadvantaged individuals. If this Congress is blocked in its effort to reform Medicaid, how long do you think it will take before the program's cost inflation has the impact you are warning about?

Mr. EDGAR. I think as Congressman Waxman pointed out, we already have real problems in Illinois under the current system, and if we don't get some major reforms, the system that is already out of control is just going to get worse and worse. I think it varies maybe from State to State, but the problem we have is we can't set what we think are the right priorities.

Again, I go back to the example of dealing with medical providers. Our hands are really tied as we try to negotiate with them and to come up with what we think is a much more cost-effective reimbursement system, so that means we don't have as many dollars to put out to as many recipients because of the rate structure we are dealing with. That is just one of many examples of where we feel that if we were given the flexibility, we could run a much more effective program and I think do a better job of providing services.

And also let me just go back I think, too, we recognize, and I think has got to be taken into consideration, this whole debate, I am sure it is on your part, is that there are limits on what the Federal Government can do. In fact, the Federal Government has probably spent more money overall than they have to spend and they have got to cut back. So we recognize that all areas are going to have to be more efficient. And we think in Medicaid that can be done and it can help our problems as well as your problems, and still provide effective care to those people who truly need it.

Mr. BLILEY. Governor Engler, what efforts has Michigan made to improve health outcomes?

Mr. ENGLER. We restructured a number of our programs. Certainly, we think managed care is part of it. We would love to have an opportunity as part of welfare reform and Medicaid reform to integrate a lot of these programs. Right now, we have programs mandated by Congress, that they really are separate.

Head Start might be an example of something we would think as an educational program ought to be somewhat coordinated with early prevention screening and detection services. The WIC program is separate from AFDC and Medicaid, and there is a great difficulty in trying to sort of knit all of these together.

We would like to have sort of a seamless system, but we are trying to do that, both with waiver and with wherever we can find flexibility. Often we run into a congressional mandate that says you can't do that or that you shall keep it separate. So we are trying to break those barriers down, barriers in large part that have followed the committee structure or subcommittee structure of the Congress and then agency preference, as opposed to a rational scheme.

So we are saying, let's try to allow us to bring these together. Specifically, one that I referred to in my testimony, a Healthy Kids Initiative is a program where we decided that we wanted to cover children in families up 150 percent of poverty regardless of whether their parents were AFDC eligible, and so we have extended that. We have a, we think, a potential population of 90,000 who might ultimately qualify. Our enrollment after a year is in excess of about 50,000. This is a population that is somewhat difficult to reach because some of these children are in working poor families but we have structured——

Mr. BILIRAKIS. Please summarize, Governor.

I am sorry, but please summarize.

Mr. ENGLER. I could go on forever.

Mr. BILIRAKIS. I could tell. That is why I asked you to summarize.

Mr. BLILEY. Thank you, Mr. Chairman.

Mr. BILIRAKIS. Mr. Dingell.

Mr. DINGELL. Thank you, Mr. Chairman.

Gentlemen, we are seeking your assistance in informing us of how we are going to restructure the process of distribution of health care funds from the Federal Government to the States to what kind of programs. The cut in the Republican budget package, as I understand it, from levels of expenditure which this country would be making in the year 2002, will be about $187 billion.

If that goes through, that means that we are going to have to share some very significant cuts. Now, each of you are going to confront the awkward problem of how you are going to do that?

First of all, not at this time, but will you submit to us your statement of what the formula should be. Today, it is a formula which is bottomed in part on the number of needy and in part the number of people in the State. And this formula in the sharing of Federal funds indicates how much money you are going to get for the administration of your respective State programs. So if you would please submit that to us, it would be of value.

Second, would you submit to us also how you propose to address the expenditure of funds. As I note in reading the way that the Republican package here is crafted, it indicates that there is going to be a cap of a 10 percent growth rate—rather a cap of an average of about 4 percent in growth rate for the several States. In point of fact, most of you have under gone a 10 percent health care cost over recent history have averaged 15 percent.

How do you propose to address this problem of growth which is going to go on despite anything you can do because of population increases, technology increases, perhaps economic downturns and the whole broad range of other things. Perhaps you could begin by answering that question specifically.

Governor Chiles, would you start off.

Mr. CHILES. Now, that question was how——

Mr. DINGELL. How are you going to address the fact that you are going to be capped at a 4 percent growth rate, when, in fact, your real growth rate has been 10 percent and the real growth rate in health care has been 15 percent?

Mr. CHILES. Well, that would be the terrible inequity of a program that was adopted that way, that capped the growth rate, that would be a total unfairness. You know, we have, as you said, the budget resolution is going to require this $185, $187 billion worth of cuts. I think that is too much coming out of Medicaid, but that is a decision that has been made.

If we are going to have that kind of cuts, I think what I would hope this committee would do is to design a program that will treat children, elderly, disabled, poor equally with how those cuts are distributed and treat States equally so that we share that burden equally. That means you have to recognize there are different growth rates, different case rates for the States.

Mr. DINGELL. The way of treating States equally is by seeing to it that the cut that each State is going to undergo is fair and that is, of course, a major concern to me.

Governor Edgar, what comments do you have on this?

Mr. EDGAR. Again, I will go back to we believe if we are given the managed care proposal we have got, we can bring down our increase. Again we were not cutting——

Mr. DINGELL. Would it bring down enough that this level of cut——

Mr. EDGAR. With that and Boren amendment repeal, the other flexibility that we would like to see, we believe that we can operate——

Mr. DINGELL. Do you know that or hope that?

Mr. EDGAR. Well, nobody knows it. We can give you things, but until you go through it——

Mr. DINGELL. So you are exercising the great Christian virtue of hope?

Mr. EDGAR. I think we do that every day in this business; don't we?

Mr. DINGELL. I don't mean to be discourteous, but that light is very cruel.

Mr. ENGLER. I am happy to get into this.

Fiscal year 1995 spending, Federal spending, is about $90 billion. No, I don't believe we are going to spend less than $90 billion in fiscal year 1996 or 1997. My understanding, we are debating how much we should increase it.

Mr. DINGELL. We are also debating on the formula of allocation amongst several States. Some States, like the State of Florida under the very able leadership of Governor Chiles, and indeed some of things you have done, you have already begun to put in place cuts.

Mr. ENGLER. Sure.

Mr. DINGELL. You are going to find that these cuts are, in fact, going to penalize you in the future and that your allocation in Michigan is going to be perhaps less favorable, because States which have not, as Governor Chiles indicates to us, taken these steps, are going to all of a sudden have to take steps, and then they are going to get a pool of money they are going to have that is not going to be available to you to provide services and care for your people.

Mr. ENGLER. I don't want to confuse efficiencies with cuts. We put efficiencies in place. We cut nothing, we spent a——

Mr. DINGELL. Efficiencies and cuts are the same thing. They are diminutions in expenditures, as Governor Chiles said.

Mr. ENGLER. My expenditure is raising the total of spending, yours and mine. Total spending has gone fiscal year 1995, $5.37 billion; fiscal year 1996, $5.88 billion. That is an increase not a decrease. But within this increase, there are a number of efficiencies to stretch that money further.

What we have got with the formula debate—and the committee needs to be very clear on, especially those of us from Michigan need to be clear that there are States out there saying, you know, if I had known that there was a prospect to block grant these funds, I would have pumped up my base a lot more. I would have spent more in order to lock in a higher amount of money.

I said, I wish I had known that. Right now, the Federal system which is getting such a stout defense here, is a system that has some States getting reimbursed 50 percent, some 83 percent and some States providing optional services, some States not providing optional services and so——

Mr. DINGELL. I apologize that light is on in the red, I want to hear, but just one quick question. You spend a substantially larger sum on a per capita basis than Governor Leavitt. I am not criticizing that he spends $500 for it. Others spend as much as $4,000 to $6,000.

Governor Leavitt what comment do you have?

Mr. LEAVITT. I would like to give you a couple examples. I mentioned in my testimony, the health claims processing that we are now doing on an electronic basis with all providers in our State. Another one perhaps the most important, is the quality initiative. Ultimately, to do this, you have got to reduce the cost of the health coverage.

We had a system in our State we are developing with all hospitals and medical providers that would be part of standards process, where we are able to, literally, at any given hospital, are be able to punch in the some symptoms and age and components of demographic importance, and you will end up with a whole series of treatment patterns that the physician then will be able to look at and determine not just what the efficiency has been in terms of treatment and what the cure rate was or the rate of efficiency, but also how much it cost. You can look in hospital to hospital and see dramatic differences in the cost, and that kind of management will ultimately reduce costs, and that is how we are able to do what we are already doing.

Mr. DINGELL. Governor, with great respect, I would observe that that does not answer the question. The question is how are you going to deal with the cuts that you are going to confront as this $187 billion comes out of a projected growth rate of 10 percent, when, in fact, the real growth rate is going to be something on the order of 15 percent and you are going to be capped at four.

Mr. LEAVITT. What we are saying——

Mr. BILIRAKIS. A real quick answer, Governor, because we are running out of time here.

Mr. DINGELL. I thank you, Mr. Chairman.

Mr. BILIRAKIS. If you have just a very few words.

Mr. DINGELL. May I make a unanimous consent request? I have a series of questions I would like to direct to our panel.

Mr. BILIRAKIS. Without objection, that would hold true on any other questions that might be asked by the members of the committee and additionally, Governor Romer was invited to attend here today and was not able to make it, and he does have a statement.

Without objection, that will be made part of the record.

[Written questions of Hon. John D. Dingell and responses follow.]

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U.S. House of Representatives
Committee on Commerce
Room 2125, Rayburn House Office Building
Washington, DC 20515–6115

June 30, 1995

The Honorable Michael Bilirakis
Chairman
Subcommittee on Health and the Environment
Committee on Commerce
U.S. House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

As you will recall in the June 8, 1995 hearing before the Subcommittee on Health and the Environment of the Committee on Commerce, I asked for unanimous consent that I be allowed to submit additional questions to the witnesses and to have the record kept open to include their responses. Because of the breadth of my request to the witnesses and the expected scope of the corresponding answers, I am requesting that the record for this hearing remain open until July 31, 1995.

Your cooperation in this matter is greatly appreciated.

Sincerely,

JOHN D. DINGELL
RANKING MEMBER

cc: The Honorable Henry A. Waxman, Ranking Member
Subcommittee on Health and the Environment

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JAMES E. DERDERIAN, CHIEF OF STAFF

U.S. House of Representatives
Committee on Commerce
Room 2125, Rayburn House Office Building
Washington, DC 20515-6115

June 30, 1995

The Honorable Lawton Chiles
Governor
State of Florida
The Capitol
Tallahassee, Florida 32399-0001

Dear Governor Chiles:

Recently, you testified before the Subcommittee on Health and the Environment of the Committee on Commerce on Federal Medicaid block grants and how they would affect your state. At that hearing you expressed concern about block grants despite claims that they would enhance flexibility in State Medicaid programs, and could result in new efficiencies that would ultimately reduce spending.

Your concerns about the block grants in the Republican's plan revolved around the fact that your state's Medicaid budget would be capped at approximately a 4 percent growth rate over the next seven years. Recent figures published by the Urban Institute for the Kaiser Commission suggest that under such a cap your state's Medicaid budget would be reduced by more than $9.8 billion for the 1996-2002 time period.

The implications of the proposed Republican plan for Medicaid are profound. Under the plan, not only would your State be forced to assume significant spending reductions, but would also undertake additional financial risk for the viability of the program. Moreover, it is not clear that most states have fully thought out even the most basic administrative requirements necessary to take on these additional responsibilities.

Given the magnitude of change proposed under the Republican plan, and the possible consequences for your state's Medicaid program, I asked unanimous consent at the June 8, 1995 hearing to submit additional questions to the witnesses and to have the record kept open to include their responses. Pursuant to that request, please provide responses to the following by July 10, 1995:

(1) The Urban Institute's analysis shows that under the Republican plan, your state could be forced to cut some 432,000 beneficiaries in the year 2002 alone. That analysis further shows that Federal spending on your state's Medicaid program would be reduced by approximately $9.8 billion over the next seven years. Do you agree with the figures in the Urban Institute's analysis? If not, please provide your own analysis of the Republican budget plan and how it will affect your state's Medicaid program. Specifically, how would an average 4 percent federal cap in the growth rate for Medicaid spending (descending to a 2% cap by 2002) affect (positively or negatively) your state's beneficiary population? Also, provide the source(s) of your analysis. If you have not already conducted this analysis and disagree with the Urban Institute's numbers, please explain your rationale for supporting such a proposal without fully evaluating how your state's Medicaid program would be affected.

(2) How do you intend to bridge any projected budgetary reductions under the Republican plan? If you intend to achieve savings through efficiencies, please describe them. How much will they save? For example, if such efficiencies include enrolling your State's Medicaid beneficiaries in managed care, what savings do you expect from such a move? If you intend to make improvements in State Medicaid administrative costs, what changes do you anticipate, and what savings do you expect? If you intend to cut beneficiaries, please report which groups you intend to cut and the expected savings. If you intend to reduce Medicaid benefits, describe which benefits you will reduce, the predicted savings, and so on. Please do this for each of the next seven years.

(3) Please provide the percentage of your state's Medicaid population that is currently enrolled in managed care and the amount you intend to enroll for each of the next seven years. Also, please provide your State's total Medicaid administrative operating costs, and the percentage of such costs in the program's total cost. Provide the most recent year, and the predicted rates for the next seven years. Also, please provide your state's Medicaid and population growth rates for each of the past 10 years, and the projected growth rates for each of the next seven years.

(4) In an April 4, 1995 report on Medicaid, GAO found that for many states a 1 percent increase in the unemployment rate resulted in a 6 percent increase in Medicaid spending (as more people lose their jobs and thus become eligible). In one State in 1991, for example, GAO found that a 2.8 percent jump in unemployment led to a 17.6 percent increase in Medicaid expenditures for that same year. This translated into a $590 million increase in total Medicaid spending for that State. Given this relationship and the increased financial risk your State will assume, please provide unemployment figures for the past 15

years. Also describe your state's contingency plan if your State faces a significant economic downturn or a sharp increase in Medicaid-eligibles.

(5) Please provide the distributional formula your administration understands will be used for determining federal contributions to your State under the proposed Republican plan. If you do not know the formula at this time, explain which factors (such as population increases, decreases, or previous spending rates) should be considered in this formula. What formulas would you consider fair? What formulas would you consider unfair? Under a block grant, which base year do you believe is appropriate to base your State's spending level? Also, provide us with an update on your State's participation in the formula-designing process (i.e., has your administration been working with the National Governors Association or other groups to generate such a formula).

(6) Please detail the specific areas where federal "micro-managing" has unnecessarily cost your state money, and then quantify those costs for each area identified. Finally, detail any expected savings that will result from removing federal involvement in each area identified.

(7) Please detail which federal laws, rules, or regulations currently govern your State's Medicaid program for which there are no overlapping or corresponding State laws. Also describe the predicted result of removing federal oversight over such areas. For example, it is my understanding that the only regulations covering home health care are Federal regulations. If federal involvement under a block grant is removed, who will provide oversight for this service? For areas where there is only federal regulation, describe whether you intend to back-fill such areas with state regulations, and the expected time tables for such actions.

Although the record for the hearing at which you testified closes on July 10, 1995, I have requested the Subcommittee Chairman extend this period until July 31, 1995, to accommodate your response. If you have any further questions on this matter, you may contact either Bridgett Taylor or Christopher Knauer of my staff at 202-226-3400. Your cooperation in this matter is greatly appreciated.

Sincerely,

JOHN D. DINGELL
RANKING MEMBER

cc: The Honorable Michael Bilirakis, Chairman
Subcommittee on Health and the Environment

The Honorable Henry A. Waxman, Ranking Member
Subcommittee on Health and the Environment

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JAMES E. DERDERIAN, CHIEF OF STAFF

U.S. House of Representatives
Committee on Commerce
Room 2125, Rayburn House Office Building
Washington, DC 20515–6115

June 30, 1995

The Honorable John Engler
Governor
State of Michigan
P.O. Box 30013
Lansing, Michigan 28909

Dear Governor Engler:

Recently, you testified before the Subcommittee on Health and the Environment of the Committee on Commerce on Federal Medicaid block grants and how they would affect our state. At that hearing you expressed support for block grants because you believed they would allow more flexibility in State Medicaid programs, and would result in new efficiencies that would ultimately reduce spending.

As you know, under the Republican plan, Michigan's Medicaid budget would be capped at a growth rate of approximately 4 percent over the next seven years. Recent figures published by the Urban Institute for the Kaiser Commission suggest that under such a cap Michigan's Medicaid budget would be reduced by more than $6 billion for the 1996-2002 time period.

The implications of the proposed Republican plan for Medicaid are profound. Under the plan, Michigan would be forced to accept significant spending reductions, and assume additional financial risk for the viability of the program. Moreover, it is clear that most states have not yet examined even the most basic administrative requirements necessary to take on these additional responsibilities.

Given the magnitude of change proposed under the Republican plan, and the possible consequences for Michigan's Medicaid program, I asked unanimous consent at the June 8, 1995 hearing to submit additional questions to the witnesses and to have the record kept open to include their responses. Pursuant to that request, please provide responses to the following questions by July 8, 1995:

(1) The Urban Institute's analysis shows that under

the Republican plan, Michigan could be forced to cut some 55,000 beneficiaries in the year 2002 alone. That analysis further shows that Federal spending on Michigan's Medicaid program would be reduced by approximately $6 billion over the next seven years. Do you agree with the figures in the Urban Institute's analysis? If not, please provide your own analysis of the Republican budget plan and how it will affect Michigan's Medicaid program. Specifically, how would an average 4 percent federal cap in the growth rate for Medicaid spending (descending to a 2% cap by 2002) affect (positively or negatively) Michigan's beneficiary population? Also, provide the source(s) of your analysis. If you have not already conducted this analysis and disagree with the Urban Institute's numbers, please explain your rationale for supporting such a proposal without fully evaluating how Michigan's Medicaid program would be affected.

(2) How do you intend to bridge any projected budgetary reductions under the Republican plan? If you intend to achieve savings through efficiencies, please describe them. How much will they save? For example, if such efficiencies include enrolling your State's Medicaid beneficiaries in managed care, what savings do you expect from such a move? If you intend to make improvements in State Medicaid administrative costs, what changes do you anticipate, and what savings do you expect? If you intend to cut beneficiaries, please report which groups you intend to cut and the expected savings. If you intend to reduce Medicaid benefits, describe which benefits you will reduce, the predicted savings, and so on. Please do this for each of the next seven years.

(3) Please provide the percentage of Michigan's Medicaid population that is currently enrolled in managed care and the amount you intend to enroll for each of the next seven years. Also, please provide Michigan's total Medicaid administrative operating costs, and the percentage of such costs in the program's total cost. Provide the most recent year, and the predicted rates for the next seven years. Also, please provide Michigan's Medicaid and population growth rates for each of the past 10 years, and the projected growth rates for each of the next seven years.

(4) In an April 4, 1995 report on Medicaid, GAO found that for many states a 1 percent increase in the unemployment rate resulted in a 6 percent increase in Medicaid spending (as more people lose their jobs and thus become eligible). In one State in 1991, for example, GAO found that a 2.8 percent jump in unemployment led to a 17.6 percent increase in Medicaid expenditures for that same year. This translated into a $590 million increase in total Medicaid spending for that State. Given this relationship and the increased financial risk Michigan will assume, please provide unemployment figures for the past 15 years. Also describe Michigan's contingency plan if Michigan faces a significant economic downturn or a sharp increase in Medicaid-eligibles.

(5) Please provide the distributional formula your administration understands will be used for determining federal contributions to Michigan under the proposed Republican plan. If you do not know the formula at this time, explain which factors (such as population increases, decreases, or previous spending rates) should be considered in this formula. What formulas would you consider fair? What formulas would you consider unfair? Under a block grant, which base year do you believe is appropriate to base Michigan's spending level? Also, provide us with an update on Michigan's participation in the formula-designing process (i.e., has your administration been working with the National Governors Association or other groups to generate such a formula).

(6) Please detail the specific areas where federal "micro-managing" has unnecessarily cost your state money, and then quantify those costs for each area identified. Finally, detail any expected savings that will result from removing federal involvement in each area identified.

(7) Please detail which federal laws, rules, or regulations currently govern Michigan's Medicaid program for which there are no overlapping or corresponding State laws. Also describe the predicted result of removing federal oversight over such areas. For example, it is my understanding that the only regulations covering home health care are Federal regulations. If federal involvement under a block grant is removed, who will provide oversight for this service? For areas where there is only federal regulation, describe whether you intend to back-fill such areas with state regulations, and the expected time tables for such actions.

Although the record for the hearing at which you testified closes on July 10, 1995, I have requested the Subcommittee Chairman extend this period until July 31, 1995, to accommodate your response. If you have any further questions on this matter, you may contact either Bridgett Taylor or Christopher Knauer of my staff at 202-226-3400. Your cooperation in this matter is greatly appreciated.

Sincerely,

JOHN D. DINGELL
RANKING MEMBER

cc: The Honorable Michael Bilirakis, Chairman
Subcommittee on Health and the Environment

The Honorable Henry A. Waxman, Ranking Member
Subcommittee on Health and the Environment

STATE OF MICHIGAN
OFFICE OF THE GOVERNOR
LANSING

JOHN ENGLER
GOVERNOR

July 31, 1995

The Honorable John D. Dingell
U.S. House of Representatives
Committee on Commerce
2125 Rayburn House Office Building
Washington, DC. 20515

Dear Congressman Dingell:

I am replying to your recent letter requesting information on Michigan's Medicaid program.

As you are well aware, the Budget Resolution calls for balancing the Federal budget by FY 2002 and, by controlling growth, Medicaid will contribute $181 billion in savings toward the balanced budget. Given that the Budget Resolution is binding, it is therefore incumbent on all of us to determine the best way to reach that goal.

Republicans have identified a block grant as the best alternative. If you have a better solution to reaching the savings in the binding Budget Resolution, I urge you to forward it.

With regard to your specific questions:

1. I reject completely the conclusions of the Urban Institute's analysis. This report presumes a "static" model. That is, the current program will remain largely intact and that the states will not institute any policy changes to ensure coverage for low-income families and individuals. In fact, this premise is completely false.

2. To plan for the implementation of a Medicaid Block Grant, a 100 member advisory group consisting of advocates, consumers, providers, and many others has been convened in Michigan to provide advice and recommendations for a new Medicaid program.

   It should be noted that an overwhelming majority of the members of this advisory group do <u>not</u> believe that the current Medicaid program should be retained as it is.

   The work of this advisory group and the development of recommendations regarding benefits, services, administration, contingency funds, and other issues is still underway.

3. Michigan has an aggressive effort to enroll recipients into managed care programs. Approximately 86% of Medicaid recipients eligible for managed care are enrolled in such a plan. Administrative costs are 4.7% in Michigan.

   Over the past several years, Medicaid has been increasing by about 10% annually. From 8% of the State general fund budget in FY 1985, Medicaid now consumes 20% of the State general fund

budget. This rate of growth is not sustainable, especially considering that State revenues that must support Medicaid grow, on average, 2.5% annually. Michigan must balance its budget annually, something Congress has only recently agreed to do.

4. See #2 above.

5. The American Public Welfare Association, under the leadership of the National Association of State Medicaid Directors, has recommended that the initial allocation to states should be each state's FY 1995 expenditures. I believe this is a fair and reasonable method to determine initial allocations. I will continue to be involved in discussions about the Medicaid formula with Governors and Members of Congress.

6. A complete list of all areas of federal micromanagement is too extensive to list here.

   Examples are:

   * Front-line workers in the Department of Social Services must administer 24 different Medicaid categories. The complex rules governing eligibility contribute to the fact that these workers spend only 20% of their time in direct contact with clients. 80% of their time is devoted to paperwork and processing information.

   * The Boren Amendment costs Michigan taxpayers over $100 million annually.

   * Between 1984 and 1993, Congress imposed over 30 new Medicaid mandates on states.

7. See #2 above. I take issue with the entire basis of your question which presumes that state governments are unable to adequately provide oversight.

Sincerely,

John Engler
Governor

JE/scp.

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JAMES E. DERDERIAN, CHIEF OF STAFF

U.S. House of Representatives
Committee on Commerce
Room 2125, Rayburn House Office Building
Washington, DC 20515-6115

June 30, 1995

The Honorable Jim Edgar
Governor
State of Illinois
State Capitol
Springfield, Illinois 62706

Dear Governor Edgar:

Recently, you testified before the Subcommittee on Health and the Environment of the Committee on Commerce on Federal Medicaid block grants and how they would affect your state. At that hearing you expressed support for block grants because you believed they would allow more flexibility in your State's Medicaid program, and would result in new efficiencies that would ultimately reduce spending.

As you know, under the Republican plan, your state's Medicaid budget would be capped at a growth rate of approximately 4 over the next seven years. Recent figures published by the Urban Institute for the Kaiser Commission suggest that under such a cap your state's Medicaid budget would be reduced by more than $6.2 billion for the 1996-2002 time period.

The implications of the proposed Republican plan for Medicaid are profound. Under the plan, your State would be forced to accept significant spending reductions, and assume additional financial risk for the viability of the program. Moreover, it is clear that most states have not yet examined even the most basic administrative requirements necessary to take on these additional responsibilities.

Given the magnitude of change proposed under the Republican plan, and the possible consequences for your state's Medicaid program, I asked unanimous consent at the June 8, 1995 hearing to submit additional questions to the witnesses and to have the record kept open to include their responses. Pursuant to that request, please provide responses to the following questions by July 8, 1995:

(1) The Urban Institute's analysis shows that under the Republican plan, your state could be forced to cut some 82,800 beneficiaries in the year 2002 alone. That analysis further shows that Federal spending on your state's Medicaid program would be reduced by approximately $6.2 billion over the next seven years. Do you agree with the figures in the Urban Institute's analysis? If not, please provide your own analysis of the Republican budget plan and how it will affect your state's Medicaid program. Specifically, how would an average 4 percent federal cap in the growth rate for Medicaid spending (descending to a 2% cap by 2002) affect (positively or negatively) your state's beneficiary population? Also, provide the source(s) of your analysis. If you have not already conducted this analysis and disagree with the Urban Institute's numbers, please explain your rationale for fully evaluating how your state's Medicaid program would be affected.

(2) How do you intend to bridge any projected budgetary reductions under the Republican plan? If you intend to achieve savings through efficiencies, please describe them. How much will they save? For example, if such efficiencies include enrolling your State's Medicaid beneficiaries in managed care, what savings do you expect from such a move? If you intend to make improvements in State Medicaid administrative costs, what changes do you anticipate, and what savings do you expect? If you intend to cut beneficiaries, please report which groups you intend to cut and the expected savings. If you intend to reduce Medicaid benefits, describe which benefits you will reduce, the predicted savings, and so on. Please do this for each of the next seven years.

(3) Please provide the percentage of your state's Medicaid population that is currently enrolled in managed care and the amount you intend to enroll for each of the next seven years. Also, please provide your State's total Medicaid administrative operating costs, and the percentage of such costs in the program's total cost. Provide the most recent year, and the predicted rates for the next seven years. Also, please provide your state's Medicaid and population growth rates for each of the past 10 years, and the projected growth rates for each of the next seven years.

(4) In an April 4, 1995 report on Medicaid, GAO found that for many states a 1 percent increase in the unemployment rate resulted in a 6 percent increase in Medicaid spending (as more people lose their jobs and thus become eligible). In one State in 1991, for example, GAO found that a 2.8 percent jump in unemployment led to a 17.6 percent increase in Medicaid expenditures for that same year. This translated into a $590 million increase in total Medicaid spending for that State. Given this relationship and the increased financial risk your State will assume, please provide unemployment figures for the past 15 years. Also describe your state's contingency plan if your State faces a significant economic downturn or a sharp increase in Medicaid-eligibles.

(5) Please provide the distributional formula your administration understands will be used for determining federal contributions to your State under the proposed Republican plan. If you do not know the formula at this time, explain which factors (such as population increases, decreases, or previous spending rates) should be considered in this formula. What formulas would you consider fair? What formulas would you consider unfair? Under a block grant, which base year do you believe is appropriate to base your State's spending level? Also, provide us with an update on your State's participation in the formula-designing process (i.e., has your administration been working with the National Governors Association or other groups to generate such a formula).

(6) Please detail the specific areas where federal "micro-managing" has unnecessarily cost your state money, and then quantify those costs for each area identified. Finally, detail any expected savings that will result from removing federal involvement in each area identified.

(7) Please detail which federal laws, rules, or regulations currently govern your State's Medicaid program for which there are no overlapping or corresponding State laws. Also describe the predicted result of removing federal oversight over such areas. For example, it is my understanding that the only regulations covering home health care are Federal regulations. If federal involvement under a block grant is removed, who will provide oversight for this service? For areas where there is only federal regulation, describe whether you intend to back-fill such areas with state regulations, and the expected time tables for such actions.

Although the record for the hearing at which you testified closes on July 10, 1995, I have requested the Subcommittee Chairman extend this period until July 31, 1995, to accommodate your response. If you have any further questions on this matter, you may contact either Bridgett Taylor or Christopher Knauer of my staff at 202-226-3400. Your cooperation in this matter is greatly appreciated.

Sincerely,

JOHN D. DINGELL
RANKING MEMBER

cc: The Honorable Michael Bilirakis, Chairman
Subcommittee on Health and the Environment

The Honorable Henry A. Waxman, Ranking Member
Subcommittee on Health and the Environment

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JAMES E. DERDERIAN, CHIEF OF STAFF

U.S. House of Representatives
Committee on Commerce
Room 2125, Rayburn House Office Building
Washington, DC 20515-6115

June 30, 1995

The Honorable Don Sundquist
Governor
State of Tennessee
State Capitol
Nashville, Tennessee 37243

Dear Governor Sundquist:

Recently, you testified before the Subcommittee on Health and the Environment of the Committee on Commerce on Federal Medicaid block grants and how they would affect your state. At that hearing you expressed support for block grants because you believed they would allow more flexibility in your State's Medicaid program, and would result in new efficiencies that would ultimately reduce spending.

As you know, under the Republican plan, your state's Medicaid budget would be capped at a growth rate of approximately 4 percent over the next seven years. Recent figures published by the Urban Institute for the Kaiser Commission suggest that under such a cap your state's Medicaid budget would be reduced by more than $5.2 billion for the 1996-2002 time period.

The implications of the proposed Republican plan for Medicaid are profound. Under the plan, your State would be forced to accept significant spending reductions, and assume additional financial risk for the viability of the program. Moreover, it is clear that most states have not yet examined even the most basic administrative requirements necessary to take on these additional responsibilities.

Given the magnitude of change proposed under the Republican plan, and the possible consequences for your state's Medicaid program, I asked unanimous consent at the June 8, 1995 hearing to submit additional questions to the witnesses and to have the record kept open to include their responses. Pursuant to that request, please provide responses to the following questions by July 8, 1995:

(1) The Urban Institute's analysis shows that under

the Republican plan, your state could be forced to cut some 114,700 beneficiaries in the year 2002 alone. That analysis further shows that Federal spending on your state's Medicaid program would be reduced by approximately $5.2 billion over the next seven years. Do you agree with the figures in the Urban Institute's analysis? If not, please provide your own analysis of the Republican budget plan and how it will affect your state's Medicaid program. Specifically, how would an average 4 percent federal cap in the growth rate for Medicaid spending (descending to a 2% cap by 2002) affect (positively or negatively) your state's beneficiary population? Also, provide the source(s) of your analysis. If you have not already conducted this analysis and disagree with the Urban Institute's numbers, please explain your rationale for supporting such a proposal without fully evaluating how your state's Medicaid program would be affected.

(2) How do you intend to bridge any projected budgetary reductions under the Republican plan? If you intend to achieve savings through efficiencies, please describe them. How much will they save? For example, if such efficiencies include enrolling your State's Medicaid beneficiaries in managed care, what savings do you expect from such a move? If you intend to make improvements in State Medicaid administrative costs, what changes do you anticipate, and what savings do you expect? If you intend to cut beneficiaries, please report which groups you intend to cut and the expected savings. If you intend to reduce Medicaid benefits, describe which benefits you will reduce, the predicted savings, and so on. Please do this for each of the next seven years.

(3) Please provide the percentage of your state's Medicaid population that is currently enrolled in managed care and the amount you intend to enroll for each of the next seven years. Also, please provide your State's total Medicaid administrative operating costs, and the percentage of such costs in the program's total cost. Provide the most recent year, and the predicted rates for the next seven years. Also, please provide your state's Medicaid and population growth rates for each of the past 10 years, and the projected growth rates for each of the next seven years.

(4) In an April 4, 1995 report on Medicaid, GAO found that for many states a 1 percent increase in the unemployment rate resulted in a 6 percent increase in Medicaid spending (as more people lose their jobs and thus become eligible). In one State in 1991, for example, GAO found that a 2.8 percent jump in unemployment led to a 17.6 percent increase in Medicaid expenditures for that same year. This translated into a $590 million increase in total Medicaid spending for that State. Given this relationship and the increased financial risk your State will assume, please provide unemployment figures for the past 15 years. Also describe your state's contingency plan if your State faces a significant economic downturn or a sharp increase in Medicaid-eligibles.

(5) Please provide the distributional formula your administration understands will be used for determining federal contributions to your State under the proposed Republican plan. If you do not know the formula at this time, explain which factors (such as population increases, decreases, or previous spending rates) should be considered in this formula. What formulas would you consider fair? What formulas would you consider unfair? Under a block grant, which base year do you believe is appropriate to base your State's spending level? Also, provide us with an update on your State's participation in the formula-designing process (i.e., has your administration been working with the National Governors Association or other groups to generate such a formula).

(6) Please detail the specific areas where federal "micro-managing" has unnecessarily cost your state money, and then quantify those costs for each area identified. Finally, detail any expected savings that will result from removing federal involvement in each area identified.

(7) Please detail which federal laws, rules, or regulations currently govern your State's Medicaid program for which there are no overlapping or corresponding State laws. Also describe the predicted result of removing federal oversight over such areas. For example, it is my understanding that the only regulations covering home health care are Federal regulations. If federal involvement under a block grant is removed, who will provide oversight for this service? For areas where there is only federal regulation, describe whether you intend to back-fill such areas with state regulations, and the expected time tables for such actions.

Although the record for the hearing at which you testified closes on July 10, 1995, I have requested the Subcommittee Chairman extend this period until July 31, 1995, to accommodate your response. If you have any further questions on this matter, you may contact either Bridgett Taylor or Christopher Knauer of my staff at 202-226-3400. Your cooperation in this matter is greatly appreciated.

Sincerely,

JOHN D. DINGELL
RANKING MEMBER

cc: The Honorable Michael Bilirakis, Chairman
Subcommittee on Health and the Environment

The Honorable Henry A. Waxman, Ranking Member
Subcommittee on Health and the Environment

ONE HUNDRED FOURTH CONGRESS

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JAMES E. DERDERIAN, CHIEF OF STAFF

U.S. House of Representatives
Committee on Commerce
Room 2125, Rayburn House Office Building
Washington, DC 20515-6115

June 30, 1995

The Honorable Mike Leavitt
Governor
State of Utah
210 State Capitol
Salt Lake City, Utah 84114

Dear Governor Leavitt:

Recently, you testified before the Subcommittee on Health and the Environment of the Committee on Commerce on Federal Medicaid block grants and how they would affect your state. At that hearing you expressed support for block grants because you believed they would allow more flexibility in your State's Medicaid program, and would result in new efficiencies that would ultimately reduce spending.

As you know, under the Republican plan, your state's Medicaid budget would be capped at a growth rate of approximately 4 percent over the next seven years. Recent figures published by the Urban Institute for the Kaiser Commission suggest that under such a cap your state's Medicaid budget would be reduced by more than $1 billion for the 1996-2002 time period.

The implications of the proposed Republican plan for Medicaid are profound. Under the plan, your State would be forced to accept significant spending reductions, and assume additional financial risk for the viability of the program. Moreover, it is clear that most states have not yet examined even the most basic administrative requirements necessary to take on these additional responsibilities.

Given the magnitude of change proposed under the Republican plan, and the possible consequences for your state's Medicaid program, I asked unanimous consent at the June 8, 1995 hearing to submit additional questions to the witnesses and to have the record kept open to include their responses. Pursuant to that request, please provide responses to the following questions by July 8, 1995:

(1) The Urban Institute's analysis shows that under the Republican plan, your state could be forced to cut some 30,500 beneficiaries in the year 2002 alone. That analysis further shows that Federal spending on your state's Medicaid program would be reduced by approximately $1 billion over the next seven years. Do you agree with the figures in the Urban Institute's analysis? If not, please provide your own analysis of the Republican budget plan and how it will affect your state's Medicaid program. Specifically, how would an average 4 percent federal cap in the growth rate for Medicaid spending (descending to a 2% cap by 2002) affect (positively or negatively) your state's beneficiary population? Also, provide the source(s) of your analysis. If you have not already conducted this analysis and disagree with the Urban Institute's numbers, please explain your rationale for supporting such a proposal without fully evaluating how your state's Medicaid program would be affected.

(2) How do you intend to bridge any projected budgetary reductions under the Republican plan? If you intend to achieve savings through efficiencies, please describe them. How much will they save? For example, if such efficiencies include enrolling your State's Medicaid beneficiaries in managed care, what savings do you expect from such a move? If you intend to make improvements in State Medicaid administrative costs, what changes do you anticipate, and what savings do you expect? If you intend to cut beneficiaries, please report which groups you intend to cut and the expected savings. If you intend to reduce Medicaid benefits, describe which benefits you will reduce, the predicted savings, and so on. Please do this for each of the next seven years.

(3) Please provide the percentage of your state's Medicaid population that is currently enrolled in managed care and the amount you intend to enroll for each of the next seven years. Also, please provide your State's total Medicaid administrative operating costs, and the percentage of such costs in the program's total cost. Provide the most recent year, and the predicted rates for the next seven years. Also, please provide your state's Medicaid and population growth rates for each of the past 10 years, and the projected growth rates for each of the next seven years.

(4) In an April 4, 1995 report on Medicaid, GAO found that for many states a 1 percent increase in the unemployment rate resulted in a 6 percent increase in Medicaid spending (as more people lose their jobs and thus become eligible). In one State in 1991, for example, GAO found that a 2.8 percent jump in unemployment led to a 17.6 percent increase in Medicaid expenditures for that same year. This translated into a $590 million increase in total Medicaid spending for that State. Given this relationship and the increased financial risk your State will assume, please provide unemployment figures for the past 15 years. Also describe your state's contingency plan if your State faces a significant economic downturn or a sharp increase in Medicaid-eligibles.

(5) Please provide the distributional formula your administration understands will be used for determining federal contributions to your State under the proposed Republican plan. If you do not know the formula at this time, explain which factors (such as population increases, decreases, or previous spending rates) should be considered in this formula. What formulas would you consider fair? What formulas would you consider unfair? Under a block grant, which base year do you believe is appropriate to base your State's spending level? Also, provide us with an update on your State's participation in the formula-designing process (i.e., has your administration been working with the National Governors Association or other groups to generate such a formula).

(6) Please detail the specific areas where federal "micro-managing" has unnecessarily cost your state money, and then quantify those costs for each area identified. Finally, detail any expected savings that will result from removing federal involvement in each area identified.

(7) Please detail which federal laws, rules, or regulations currently govern your State's Medicaid program for which there are no overlapping or corresponding State laws. Also describe the predicted result of removing federal oversight over such areas. For example, it is my understanding that the only regulations covering home health care are Federal regulations. If federal involvement under a block grant is removed, who will provide oversight for this service? For areas where there is only federal regulation, describe whether you intend to back-fill such areas with state regulations, and the expected time tables for such actions.

Although the record for the hearing at which you testified closes on July 10, 1995, I have requested the Subcommittee Chairman extend this period until July 31, 1995, to accommodate your response. If you have any further questions on this matter, you may contact either Bridgett Taylor or Christopher Knauer of my staff at 202-226-3400. Your cooperation in this matter is greatly appreciated.

Sincerely,

JOHN D. DINGELL
RANKING MEMBER

cc: The Honorable Michael Bilirakis, Chairman
Subcommittee on Health and the Environment

The Honorable Henry A. Waxman, Ranking Member
Subcommittee on Health and the Environment

LAWTON CHILES
GOVERNOR

STATE OF FLORIDA
Office of the Governor
THE CAPITOL
TALLAHASSEE, FLORIDA 32399-0001

July 28, 1995

The Honorable John D. Dingell
U.S. House of Representatives
Committee on Commerce
Room 2125, Rayburn House Office Building
Washington, D.C. 20515-6115

Dear Representative Dingell:

Thank you for the opportunity to answer additional questions regarding the impact of the Republican plan on Florida's Medicaid program. I have attached detailed responses to the seven questions that were forwarded to me.

As my responses make clear, the Republican plan would devastate Florida's Medicaid program. The loss of at least $8.1 billion in federal funds would necessitate deep cuts in state programs by the Legislature. Florida already provides fewer coverages and pays it providers less than most Medicaid programs. The Republican proposal will force even greater reductions in coverages and services. We cannot tolerate this.

I hope that this information fully answers your questions. Please feel free to contact me if additional information is required. And thank you once again for allowing me to detail how Florida will be adversely affected by the Republican plan.

With kind regards, I am

Sincerely,

Lawton Chiles

LAWTON CHILES

LC/msc/wc

attachments

(1) *The Urban Institute's analysis shows that under the Republican plan, Florida could be forced to cut some 432,000 beneficiaries in the year 2002 alone. That analysis further shows that Federal spending on Florida's Medicaid program would be reduced by approximately $9.8 billion over the next seven years. Do you agree with the figures in the Urban Institute's analysis? If not, please provide your own analysis of the Republican budget plan and how it will affect your state's Medicaid program. Specifically, how would an average 4 percent federal cap in the growth rate for Medicaid spending (descending to a 2% cap by 2002) affect (positively or negatively) Florida's beneficiary population. Also, provide the source(s) of your analysis. If you have not already conducted this analysis and disagree with the Urban Institute's numbers, please explain your rationale for supporting such a proposal without fully evaluating how Florida's program would be affected.*

Based on the concurrent budget resolution which establishes FY 1994-95 as the base year for the Medicaid block grant and allows each state's Medicaid expenditures to grow by 7.2 percent in the first year, 6.8 percent in the second year and 4 percent for the remaining five years, Florida Medicaid estimates the cumulative loss over the seven state fiscal years to be about $8.1 billion. By comparison, the Urban Institute's estimate of federal funding reductions in Florida is $9.8 billion. The Urban Institute estimate is based on the House Budget Resolution, which reduces the federal spending cap quicker than the concurrent budget resolution.

A four percent federal cap on Medicaid spending increases, beginning in the first year of the block grant and descending to a two percent cap by 2002, would further reduce federal funding for Florida's Medicaid program by $3.3 billion over the seven-year period, increasing the federal funding reduction to $11.38 billion.

A federal funding reduction of this magnitude would reduce the number of unduplicated Medicaid recipients by 371,118 by state fiscal year 2001-02, even assuming that we are able to hold cost per person to 1995-96 levels by reducing benefits, reimbursement and any savings that we may realize.

Projected Costs Assuming a 12 percent Rate of Growth in SFY 2001-02	$13,243,386,464
Average Cost Per Person in the Year 2002	$5,628
Estimated Beneficiaries in Year 2002	2,353,124
Projected Program Costs under Block Grant Proposal in Year 2002	$8,548,867,891
Estimated Beneficiaries in Year 2002 Program Could Afford under Block Grant	2,035,929
Unduplicated Recipients	371,118
Estimated Cut in Enrollment (Including the Reduction of Services and the Implementation of StatewideManaged Care Enrollment)	317,195

(2) *How do you intend to bridge any projected budgetary reductions under the Republican plan? If you intend to achieve savings through efficiencies, please describe them. How much will they save? For example, if such efficiencies include enrolling Florida's Medicaid beneficiaries in managed care, what savings do you expect? If you intend to cut beneficiaries, please report which groups you intend to cut and the expected savings. If you intend to reduce Medicaid benefits, describe which benefits you will reduce, the predicted savings, and so on. Please do this for each of the next seven years.*

Florida ranks 44th in the nation in Medicaid cost per recipient. Florida Medicaid provides fewer coverages and pays its providers less than most other state Medicaid programs. But under the Republican proposal, Florida will be required to further reduce eligibility coverages, decrease services, eliminate services, decrease provider payment levels, and increase recipient cost sharing. Florida's Medicaid cost per enrollee is $2,368 and is one of the lowest in the nation, therefore, these reductions would further prevent Florida from increasing the cost per enrollee and penalize states like Florida who have been efficient in the administration of their Medicaid program. Florida Medicaid has already enrolled over 605,000 recipients in managed care programs, approximately 38 percent of the total caseload. About 413,000 recipients are enrolled in HMOs and 192,000 recipients are enrolled in MediPass, Florida's primary care case management system. Any combination of these program cuts will have a devastating impact on all Floridians and will result in a major cost-shift to our government and taxpayers.

Florida has not yet developed proposals of how the state would adjust to the loss of $8.1 billion in federal funds. Program reductions would have to be enacted by the Florida Legislature.

(3) Please provide the percentage of Florida's Medicaid population that is currently enrolled in managed care and the amount you intend to enroll for each of the next seven years. Also, please provide Florida's total Medicaid administrative operating costs, and the percentage of such costs in the program's total cost. Provide the most recent year, and the predicted rates for the next seven years. Also, please provide Florida's Medicaid and population growth rates for each of the past 10 years, and the projected growth rates for each of the next seven years.

See response to question 4 for historical Medicaid and population growth for the past 10 years.

Florida's Medicaid Managed Care Program and State Population Estimates From FY 1995 To FY 2000						
	FY 1994-95	FY 1995-96	FY 1996-97	FY 1997-98	FY 1998-99	FY 1999-00
STATE POPULATION	14,244,900	14,516,500	14,786,200	14,15,057,100	15,326,400	15,594,100
GROWTH RATES	2.1%	1.9%	1.9%	1.8%	1.8%	1.7%
MEDICAID CASELOAD	1,581,631	1,612,293	1,687,646	1,765,823	1,846,990	1,931,318
GROWTH RATES		1.9%	4.7%	4.6%	4.6%	4.6%
PERCENT ENROLLED IN MANAGED CARE	38.27%	70.00%	80.00%	93.00%	93.00%	93.00%
HMO	413,534	770,969	449,994	546,679	571,994	598,110
MEDIPASS	191,829	357,636	900,123	1,095,536	1,145,707	1,198,016
MANAGED CARE	605,363	1,128,605	1,350,117	1,642,215	1,717,701	1,796,126

Note: Institutional clients are not anticipated to be in managed care(i.e. nursing home, etc.)

Florida's Medicaid Program Administrative Costs (in billions)									
	FY 93-94	FY 94-95	FY 95-96	FY 96-97	FY 97-98	FY 98-99	FY 99-00	FY 00-01	FY 01-02
ADMINIST RATION	0.146	0.144	0.15	0.156	0.162	0.168	0.175	0.18	0.189
MEDICAL SERVICES	5.212	5.824	6.709	7.514	8.416	9.426	10.557	11.8	13.243
TOTAL	5.358	5.968	6.859	7.67	8.578	9.594	10.732	11.98	13.432
ADMINIST RATION AS A PERCENT OF TOTAL	2.72%	2.41%	2.19%	2.03%	1.89%	1.75%	1.63%	1.50%	1.41%

Notes: FFY 1993-94 - Actual HCFA 64 Report
FFY 1994-95 - Three quarters Actuals - Straight -lined
FFY 1995-96 - on services form chart

(4) In an April 4, 1995 report on Medicaid, GAO found that for many states a 1 percent increase in the unemployment rate resulted in a 6 percent increase in Medicaid spending (as more people lose their jobs and thus become eligible). In one state in 1991, for example, GAO found that a 2.8 percent jump in unemployment led to a 17.6 percent increase in Medicaid expenditures for that same year. This translated into a $590 million increase in total Medicaid spending for that State. Given this relationship and the increased financial risk Florida will assume, please provide unemployment figures for the past 15 years. Also, describe Florida's contingency plan if Florida faces a significant economic downturn or a sharp increase in Medicaid eligibles.

State of Florida Current Population Survey Annual Averages						
Fiscal Year	Population Estimates	Population Growth	Unemployment	Unemployment Rate	Medicaid Expenditures	Medicaid Eligibles
1980	9,845,140		251,000	5.9%		458,719
1981	10,217,200	3.8%	308,000	6.8%		498,343
1982	10,490,900	2.7%	388,000	8.2%		505,601
1983	10,751,400	2.5%	424,000	8.6%		488,376
1984	11,067,300	2.9%	325,000	6.3%	795,222,668	496,229
1985	11,404,900	3.1%	320,000	6.0%	913,687,253	494,118
1986	11,740,800	2.9%	320,000	5.7%	1,034,864,496	513,449
1987	12,082,600	2.9%	312,000	5.3%	1,212,448,111	546,598
1988	12,409,600	2.7%	304,000	5.0%	1,512,234,584	592,894
1989	12,724,500	2.5%	348,000	5.6%	1,946,681,608	655,744
1990	13,004,700	2.2%	383,000	5.9%	2,495,994,505	762,223
1991	13,250,200	1.9%	473,000	7.3%	3,174,477,439	922,038
1992	13,452,800	1.5%	535,000	8.2%	3,986,462,474	1,176,350
1993	13,673,600	1.6%	463,000	7.0%	4,852,425,216	1,478,393
1994	13,955,300	2.1%	448,000	6.6%	5,889,171,821	1,602,660

Florida is subject to increases in AFDC during a recession. Any economic downturns, increases in unemployment rates, and corresponding increases in Medicaid eligibles would require further reductions in eligibility and/or service coverages.

(5) Please provide the distributional formula your administration understands will be used for determining federal contributions to Florida under the proposed Republican plan. If you do not know the formula at this time, explain which factors (such as population increases, decreases, or previous spending rates) should be considered in this formula. What formulas would you consider fair? What formulas would you consider unfair? Under a block grant, which base year do you believe is appropriate to base Florida's spending level? Also, provide us with an update on Florida's participation in the formula-designing process (i.e., has your administration been working with the National Governors Association or other groups to generate such a formula).

An allocation formula that allocates federal Medicaid funding to the states under a uniform growth cap would be inequitable for high growth states or states with disproportionately high elder, poverty, and uninsured populations and lower revenue raising capabilities. Also, the uniform cap will be inequitable for states that already have implemented managed care because their base is understated. In addition, no distribution formula should be applied to states with waivers. These states should be allowed to grow based upon the rates of increase specified within the contract with the federal government.

If a Medicaid block grant is enacted, the distributional formula must account for differences in the aged, blind and disabled population and the percent of people below poverty. These two factors could be weighted as follows: Aged, Blind and Disabled population (60%) and percentage of state population with incomes below the federal poverty level (40%).

(6) *Please detail the specified areas where federal "micro-managing" has unnecessarily cost your state money, and then quantify those costs for each area identified. Finally, detail any expected savings that will result from removing federal involvement in each area identified.*

The following federal statutes/regulations are examples of federal micromanagement that have increased state and federal Medicaid costs without increasing access or the quality of care:

- Categorical eligibility restrictions
- HMO commercial enrollment requirements
- 1915(b) waiver two-year renewal cycle
- Boren Amendment
- OBRA '90 mandated drug coverage for manufacturers agreeing to rebates
- Prohibition of the substitution of full state Medicaid benefits in lieu of coverage of dual eligibles' Medicare premiums, deductibles, and coinsurance benefits
- Medicaid audit and disallowance policies
- Program documentation requirements
- 1915(b) and home and community-based waivers (allow states to establish as optional services rather than requiring waivers)
- Cost-sharing limitations

(7) *Please detail which federal laws, rules, or regulations currently govern Florida's Medicaid program for which there are no overlapping or corresponding state laws. Also describe the predicted result of removing federal oversight over such areas. For example, it is my understanding that the only regulations covering home health care are Federal regulations. If federal involvement under a block grant is removed, who will provide oversight for this service? For areas where there is only federal regulation, describe whether you intend to back-fill such areas with state regulations, and the expected time tables for such actions.*

State law specifies Medicaid program eligibility and service coverages, recipient cost sharing limitations, Medicaid prepaid plan requirements, fraud and abuse program requirements, and other essential program features. State law does not generally specify provider reimbursement, program documentation, and other eligibility, service, and administrative details that are generally contained in federal statutes and regulations. State rules address these issues. The states, however, are fully capable of adopting state regulations and policies to govern all aspects of their programs. Typically, it would require legislative action and take a minimum of one year to implement the repeal of such regulations.

STATE OF TENNESSEE

DON SUNDQUIST
GOVERNOR

July 14, 1995

The Honorable John D. Dingell, M.C.
U.S. House of Representatives
Committee on Commerce
Room 2125, Rayburn House Office Building
Washington, D.C. 20515

Dear John:

I thank you for writing me regarding my recent testimony on the Medicaid block grant being examined by the Committee on Commerce. It was good to see you and a number of my former colleagues and to let you know about our experience with Medicaid issues in Tennessee and the Section 1115 waiver under which we operate the TennCare program.

While I understand from the tenor of your questions that you take issue with some aspects of the majority plan for Medicaid reform, I wish to stand on my testimony and to reiterate that Tennessee has the answer to its Medicaid issues.

The General Accounting Office has identified Tennessee as the ONLY state with a budget neutral waiver. During the fiscal year just ended, we operated the TennCare program at a cost of almost one billion dollars less - that's 25 per cent less - than the old Medicaid program would have cost, while expanding the population served by 50 per cent. That's a direct savings in federal funds alone of more than $650 million in one year. And, while serving the 800,000 Tennesseans formerly under the old Medicaid program, we also added 400,000 working poor who formerly had no insurance.

Among all states, Tennessee has the highest percentage of citizens with health insurance - at about 95 percent. We can continue to operate such a program under the majority's block grant plan and are committed to doing that. We support continued recognition of the existing waivers, such as TennCare, until their expiration. We support the capping of the program at reasonable levels which recognize the planned, controlled growth which we have allowed in Tennessee.

It was good to hear from you again.

Sincerely,

Don

Don Sundquist

State Capitol, Nashville, Tennessee 37243-0001
Telephone No. (615) 741-2001

Mr. BILIRAKIS. These gentlemen I understand have to leave approximately at noon. We are going to have to hold to that 5-minute rule.

So Mr. Upton.

Mr. UPTON. Well thank you, Mr. Chairman, and I will try to keep my questions limited to 5 minutes.

Governor Engler, I think you were correct when you started beginning to talk about the increase in Medicaid. The number I have for the budget resolution that passed the House several weeks ago, and I do expect that the change in the number probably to get higher, because in 1995, we are spending almost $90 billion in Medicaid from the Federal perspective. By the year 2002 that $90 billion, in fact, grows to $125 billion.

What I hear from Governors like yourself is that if we can in fact block grant these dollars to the States and by making some changes, whether it is repealing the Boren amendment, as Governor Edgar suggested, in fact, you can live within that framework as long as you have the flexibility.

I wanted to focus a little bit on the Boren amendment itself. You indicated in your testimony, I believe, that the Boren amendment required you to reimburse nursing homes not at the $35 per patient, per day rate that you had earlier, but in fact increase that to $57 per patient, per day. What is the cost for that change under the Boren amendment in terms of what the State of Michigan had to do?

Mr. ENGLER. Total spending budget of the Boren amendment, about $238 million more Statewide $105 million of that covered by the State; $133 million of it covered by the Federal Government.

Mr. UPTON. Am I correct in that you are stating that Michigan would be a State that would be certainly willing to live under a block grant scenario knowing in fact the dollars are going up and not going down?

Mr. ENGLER. One scenario that I saw, Congressman, was that under the House Budget Resolution, you could possibly have cap growth that might be 8 percent in year 1, maybe 5.5 percent in year 2, and then 4 percent after that. The Senate number is a little bit different.

In contrast, I mean, we have got private health care organizations today that, in some cases, are rebating back, cutting their costs, are lower than zero. I mean, they are rebating. We have others that held to 1, 2 and 3 percent. Maybe there is an assumption in Washington that because it is a public program, it always has to grow at some factor of *X* plus 2 or 3 or more percent than private sector comparable plans.

I would argue, though, just to emphasize the point that you have to give us all the flexibility. We can't get there if you say, well, let's keep a part of the Boren amendment or a part of the OBRA requirements, or as Congressman Waxman asked earlier, to address that we ought to cover—he suggested we ought to cover disabled, children, families. I don't mind being told we ought to cover. I suspect if it got written down by a staff, it might say we shall do this and there might not be flexibility and we might have HCFA helping us run the program. That won't work.

Mr. UPTON. We heard from Governor Sundquist who, unfortunately, had to leave, and he was talking about his 1115 waiver program, and I see the material that a number of my colleagues have brought in terms of what it requires to get an 1115 program. It is my understanding that States are using that as a laboratory to improve their type of system. I don't believe that Michigan has moved toward that seeking such a waiver? And I wonder if I might ask what plans Michigan may have with regard to that and if they are not planning to seek such, why, other than the stack of paper.

Mr. ENGLER. We already have 82 percent of our Medicaid population currently in managed care under the way we are running the program, so we are in fine shape.

Mr. UPTON. So you don't expect Michigan to proceed on that at all?

Mr. ENGLER. I think we are sort of beyond that point. Different States are at different stages, but every time somebody wants to change something, Governor Chiles has got an idea, any one of the Governors, we all have got this paperwork. This will go away and who else ought to go away are the bureaucrats who are the receiving end of this paper.

Mr. UPTON. I have had a number of groups come to my office during the discussion of Medicaid reform seeking a certain percentage of money to protect "vulnerable populations" whether it be women, infants, children, elderly, mentally ill, do you think that is something we ought to take a serious look at or should we not do that at all and allow the States to have the flexibility?

Mr. ENGLER. You should not do that at all. You should refer to places like Sacramento, Tallahassee, and Lansing. There are great places to visit and they can be heard there.

Mr. UPTON. Thank you very much.

Mr. BILIRAKIS. Mr. Wyden.

Mr. WYDEN. Thank you, Mr. Chairman.

I am troubled by many features of the Republican plan. I think it is really cut first, and ask questions later. But I know that the Governors on this side of the table would take exception to that characterization.

But what I think is especially distressing is we are headed for a monumental battle royal over this distribution of Federal funds, and it seems to me that the core of making a block grant proposal work is the fair distribution of Federal funds, and as far as I can tell, the Governors don't agree on what would be a fair distribution of Federal funds.

Does the National Governors Association have a position at this point as to what would constitute a fair distribution of Federal funds so we can begin to debate this in a thoughtful way rather than just prepare for a bloodbath where the poor get hurt?

Mr. EDGAR. First, I don't think anyone could properly say we all think the current distribution formula is good.

Mr. WYDEN. Does the National Governors Association have a position?

Mr. EDGAR. That is part of the discussion going on right now. But again, I would argue as a State that gets one of the smallest amounts of match back from the Federal Government for Medicaid, I am not crazy about the current formula.

I appreciate Governor Chiles' concern about a growth State and how that might be in the future. I don't think there is any doubt that is an issue that is going to be a thorny issue.

I think that is a separate issue than talking about flexibility. There are a variety of issues you need to deal with when you look at Medicaid.

We are in the process of trying to reach some consensus, but I think ours would be very similar to what you might reach because you represent the various States and some might feel that they ought to get more than others. Again, I would go back, I don't think we ought to lose sight—I think we all pretty well agree we need to be given the flexibility no matter what the formula is.

Mr. ENGLER. I might just add that everybody has set their current amount of distribution, if you will, because we have the opportunity to set our program in terms of the scope of benefits and the amount of spending. You currently match that.

So I felt that the fair starting point is to take people where we find them. I would certainly disagree with some of the congressional decisions which reflect the lack of a consensus in Congress on a fair funding formula. I mean, what you have cobbled together over the years is anything but fair, but it is what we have, so my rationale simply is to take people where you find them and let's go forward from there. And they are there, because that is where they chose to be.

Mr. CHILES. That is a good rationale of somebody who finds himself in a pretty good place at the time.

Mr. WYDEN. You know, I just think that this is all fine in theory and maybe people are going to hustle in the next few months to change to get ready for it. But what is going to happen is these decisions are going to be made on raw political power. And who has got the clout is going to be more important than the needs of the poor, and in my State, for example, Governor Engler, we made the most gutsy decisions in America about the nature of health care.

We have been the only State that has been willing to make some tough calls about priorities. And under what you all are talking about, it seems to me, we are going to get hurt pretty bad, and it just really makes this member especially distressed that all of you will talk about theory, which is great, and I am anxious to do it, but when it comes to working with us to devise a fair formula distribution plan, everybody says, well, we don't much like today's system and we will just see what happens.

Mr. EDGAR. Congressman, we are here. We are willing to work.

Mr. WYDEN. That is why I asked if the National Governors Association will come to a consensus.

Mr. EDGAR. Can you come to a consensus in Congress? You have got a geographic split, and that is very difficult. Any time you deal with a formula, you are going to change the current formula that is going to add to the difficulty.

I guess what we are saying, some of us would argue, I am not crazy about the current formula, but I do know the flexibility issue is something we do come to consensus on and something you can move on. I appreciate the fact that Governors want to see something happen on formula.

We are willing to enter into that discussion, but I think Congress has the same problem we have as Governors, because it is different States.

Mr. WYDEN. We are willing to work with all of you, but the point is this is going to be the overriding issue. You know my State, we are practically the poster child for managed care, but Kaiser said it is only going to save 1 percent to 2 percent of total expenditures. We are not going to do it on managed care, Governor. We are going to have to come up with a fair formula for distribution. If we don't, the poor are just going to be shocked.

Mr. BILIRAKIS. The gentleman's time has expired.

Dr. Coburn.

Mr. COBURN. Thank you, Mr. Chairman.

I am somewhat confused, I have extrapolated from your handout on EPSDT, the CBO score of $25 million, and then extrapolated that to $63 million, and the $3.8 from Florida, which came up to $1.7 billion.

And Congressman Wyden talked about theory, I want to share as a practicing physician the theory of Medicaid today. When EPSDT was put out, I was seeing Medicaid infants at 2 months, 4 months and 6 months and charging the State of Oklahoma $16 to do that, and was happy to do that.

When this came through, there came requirements that said a certain number of children, for them to continue to get matching funds, had to go through this EPSDT formula. For the State of Oklahoma to continue to receive funds, guess what they did?

They wanted a piece of paper filled out so that they could qualify for what the Federal requirements were for treating newborns, 2 months, 4 months, 6 months, young children, so they said fill out this form, and instead of paying you $16, we will pay you $72, so we can get you to fill out the form.

Well, that happened all over this country. What we were trying to do was take care of more children. We took dollars based on what a government-mandated stipulation said and took money away from other people, and put it in the provider's pocket.

So the theory, I don't believe there is anybody sitting out there right now that doesn't want to take care of young children, that doesn't want to take care of pregnant women, that doesn't want to care for the disabled and those that have not. The question comes, who is best to do it?

You know, this is just one example of my own experience in dealing with Medicaid. I am sure you all have hundreds and even more within your own bureaucracy in your State. But my question comes to you is, what is the guarantee that you are going to run it any better than the Federal Government is going to run it?

What is the motivation that is going to allow you to run it better and to meet those very people that Congressman Waxman asked about? Where is the guarantee?

Mr. EDGAR. Well, first of all, we are already given the responsibility to administer the program. What we would like to be able to do is to manage the program.

It is really tough to administer a program you can't control, and I think everybody would agree the current system doesn't work. We

may not agree on the solution of fixing it, but I think we all agree it doesn't work.

The whole theory behind 50 States originally was States were to experiment to try and every State is not going to be perfect. We are saying, take a program that doesn't work, that is broken, that is out of control and let us try at the State level.

As far as accountability, again I will repeat, we are accountable to the same people that you are. The same people that elect Congress, the same people that elect the President, elect State legislators and Governors. And it is not that you are going to say we are going to turn this over to you and we are not accountable. We are.

But again, I will go back, the current system doesn't work, let's try letting the States who have to run the program actually have control of the program, and I think we could do a better job.

Mr. COBURN. Let me ask one additional question.

Mr. LEAVITT. May I comment briefly on that just briefly. Let me tell you about the Medicaid recipient mother with three children recently that I had a chance to review the file on, who quit her job because it was the only way she could gain access to Medicaid, and she is now back on AFDC and food stamps in my State.

Given the capacity, we are talking about Medicaid, but what we are looking for is not just the ability to run the Medicaid program, we are looking for a chance to take all of these programs that serve the poor and the needy in our States and weave them into something that makes sense, instead of this latticework of programs that have overlapping eligibility that don't weave together well. This is not just one piece of the pie, this is the whole pie we are looking for.

Mr. COBURN. Each of you, obviously, thinks that there are large savings that can be made by changing the system. And as somebody that comes from a provider in the system, I can't agree with you more, and I think the last place we ought to have a Medicaid run system is the Federal Government.

And as a matter of fact, I am not even sure we should do it at the State government level. We might ought to do at the county government level.

The point is, the closer we get that decision to the people that are actually giving the care and responsible for the people that have a need, then the more accurate and more efficient and more cost-effective we might be.

I don't have any additional questions.

Mr. BILIRAKIS. The gentleman's time has expired.

I thank the gentleman.

Mr. Stupak.

Mr. STUPAK. Thank you, Mr. Chairman.

Governor Engler, according to the Kaiser Report that Mr. Waxman mentioned, underneath the current House budget proposal, our State would lose about $6 billion between 1996 and 2002. That loss of money, according to the Kaiser Commission, would mean that there are about 16,000 elderly, about 44,000 disabled, and about 162,000 low-income families that would probably go without services because of these reductions. If we give you the flexibility, how would you then decide who would be covered and what would happen to those who would be left out?

Mr. ENGLER. Thank you, Congressman, for asking the question. We disagree with the Kaiser Report completely. We don't think it represents Michigan, and so I am glad you have asked that. We don't feel that that lack of coverage would be present at all.

In fact, we fear more that this Congress would somehow deadlock on this issue and at the end of the day, at the end of the fiscal year, you might reduce by 5 or 10 percent the current program and that would do exactly what Kaiser is suggesting. That is the real threat. That is where people might lose coverage.

If we have the flexibility with managed care, if we have the flexibility to restructure programs, if we have the ability to enter into relationships with providers across the State, we are going to continue to have the success that we have enjoyed with the program.

And to Congressman Wyden, while I have got the microphone, the National Association of State Medicaid Directors, yesterday—we just received this this morning, we haven't hadn't a chance to see it—unanimously approved in a policy, recommendations on Medicaid reform the following statement—these represent all the States. They aren't men and women who run for office, they are just the technicians: This year, fiscal year 1995, should be the base year for establishing Federal financial obligation. The base year figures shall be based on a State's total expenditures for fiscal year 1995, including Federal expenditures associated with all waivers and significant State plan amendments as though implemented for a full year.

So now we can tell you there is an agreement out. It is the Medicaid directors, the only experts that run the program, but if they have got any credibility, we would offer that, and I will submit a copy to the committee.

Mr. STUPAK. Let me reclaim my time, and Mr. Chairman, I hope you charge that to Mr. Wyden and not to my time.

To follow up on your question, my understanding is Michigan has a 2 percent administrative cost in the Medicaid program. And you claimed in earlier testimony, you have 82 percent of your people on managed care. Where are you going to squeeze the savings in to make up for the $6 billion you will lose?

Mr. ENGLER. We are not going to lose $6 billion. That number is false.

Mr. STUPAK. Well, then answer this question for me; how much are you going to lose?

Mr. ENGLER. We will have an increase. No proposal spending before Congress reduces Medicaid expenditures.

Mr. STUPAK. So you are claiming then that you will see——

Mr. ENGLER. I am using your data to make the statement.

Mr. STUPAK. You will be able to provide for all these people.

Mr. ENGLER. The increases that you will provide us in revenues will allow us to continue to expand services as we improve the management of the program because we will now have control of the programs as opposed to having HCFA bureaucrats trying to run it from Washington and telling us that the program in the upper peninsula of Michigan, which you are familiar with, is the same program we need for Detroit.

You know from your own experience in the State of Michigan, a program in Detroit is different than a program in Marquette, but

the HCFA people don't know the difference between Detroit and Detour or Marquette, and so they think it is the same program. They are wrong.

Mr. STUPAK. Governor, you know, I have some problems here. Your increase for needs for Medicaid in the State of Michigan, and I remember just a short time ago that we had the DSP program where Congress closed that because it was being used for other than its intended purposes under Medicaid, and Michigan lost about $250 million, and you wrote us all a letter complaining bitterly about the loss of $250 million.

Now, you are going to lose $6 billion and you are telling us those are false figures and they don't count, and that is okay. How do you reconcile that when you write us about $250 million as opposed to $6 billion?

Mr. ENGLER. I would be happy to provide a detailed breakout of Michigan Medicaid expenditures which show Federal spending, and State spending, and the total spending. It shows that in each year, we are spending more, with the State government, or the Federal Government, and combined, than we have spent in the previous year.

We certainly try to fully comply with Federal law. We have done that with DSP payments. We have done that with everything that we can to interpret the law to raise reimbursement rates.

We think that the Congress has for a number of years tolerated very unfair funding formulas. Why would we pay State A, 83 percent of their costs, how could you let that happen when some other States only gets 50 percent paid? But as long as that is going on, that is the law, we follow the law.

Mr. BILIRAKIS. The gentleman's time has expired.

Dr. Ganske.

Mr. GANSKE. Thank you, Mr. Chairman.

I ask unanimous consent to introduce a statement, including a letter from Governor Branstad affirming what several of the Governors have said today.

I found a series of articles in The Washington Post concerning this issue to be very informative. This committee will be very instrumental in what we are talking about today.

Between 1984 and 1990, this committee rushed through a series of provisions that expanded benefits and increased the number of people covered. And it is for that reason, as well as some others, that we have had an explosion in Medicaid costs. And in fairness to the committee, the States have also had a part in this explosion of costs.

I attended a hearing in which June O'Neill, Director of the CBO, testified, and, to put it charitably, some State governments have found rather creative ways to extract more Federal dollars from the program. And lobbyists and advocates for the poor have exerted a relentless pressure on Congress to expand benefits, so, in essence, what we have had is a significantly expanded package, but we have had a Congress that hasn't been willing to pay for it. And so costs have been shifted from one side to the other side.

So that brings us to I think what we are talking about today. I agree with Representative Wyden. I think one of the big issues that we will be facing if we are talking about a block grant approach,

whether you agree with a block grant approach or not, is the issue of fairness in terms of distribution of those funds across the States.

Iowa, for instance, like some other States, did not game the system and has done a fairly good job trying to reduce expenditures and control costs. Consequently, the State of Iowa receives one-third the Federal dollars per recipient that some other States do.

I would like to ask the three remaining Governors, how do you think Congress should address this issue? I mean, how are we going to even this out? Should we go to a regional review? Should we look at a national average and have some variance built into this? I really think that this is a very significant issue with the block grant approach.

Mr. ENGLER. Let me just try to again get us back to where we are. We have a formula today. We have a law which allows for distribution, and so if we weren't here talking about block grants, we are merely talking about reauthorization of Medicaid funding for next year, would we be in a formula debate?

I mean, maybe we would and maybe we wouldn't. But we have a formula which is a baseline. So I think there are those groups out there who want no reform, who work very hard to divert you into this fight about the formula in order to have you overlook conveniently repealing OBRA, repealing Boren, repealing rules and regulations that hamper our freedom and flexibility.

So I think that in the formula debate—and I just read a paragraph from the Medicaid directors report adopted unanimously that said let's start and use 1995. That is the year. We can't do anything about this year.

Let's use that as the base and go forward with the new money you are going to spend. Then look at how you would spend that and I think that gets us into the debate.

But right now, any State under the current system could raise its Federal reimbursement if it decided to raise its State expenditures. It is all tied off of that. And we think we have saved money for the Federal Government because we have had an incentive to save money in our State budget. We are going to leave money on the table under the reforms that we are making. That is just the way it works.

Mr. GANSKE. Governor Leavitt?

Mr. LEAVITT. I have problems with the education formula. I have problems with the transportation formula. I come from a State with five members of our entire congressional delegation. You won't find a formula I don't have problems with.

My guess is you can't get into a discussion of formula without having what the Congressman calls a bloody political debate. I suspect it will happen. That is the public decisionmaking process.

I am one, like Governor Chiles, I have a State that is growing at 2.7 percent a year. I am going to have significant growth.

I believe we have to deal with that if we get into the formula issue. But what I am concerned about right now is having the ability to do better with what I have. We can do significantly better with the resources that we have.

Mr. BILIRAKIS. The gentleman's time has expired.

Mr. Deutsch.

Mr. DEUTSCH. Thank you, Mr. Chairman.

I guess it is maybe from where you sit and what you see, but really following up on what Governor Chiles had talked about, the two issues which really seem to have an incredibly adverse potential impact on Florida.

And I was happy to hear the chairman's statement that the Budget Committee's recommendation of the 5 percent cap across the board by State is something that basically this committee, the subcommittee is not going to take very seriously in and of itself. I guess I would direct the question to Governor Chiles, just give him the opportunity to respond, specifically, and also Governor Leavitt mentioned as well, if you could give us a proposal, and I know it would be a painful exercise, but assuming the $187 billion cut over that period of time, trying to come up from your perspective with something more equitable dealing with the growth factor.

Again, I don't think you need to be an MIT economist to figure out that the situation of States that are not growing versus the situation of States that are growing exponentially, a small State like Utah as well as a large State like Florida, is just going to create incredible unacceptable inequities, and I find it difficult that any member that supported the budget resolution with the 5 percent cap, and Florida is a State with 23 Members of the House, in and of itself would have supported that resolution, and the majority of our members did.

So the second half of the question is really an innovation. Congressman Wyden mentioned the inroads that the State of Oregon has made. I would put Florida's record in creative and efficient and successful innovations against any State in the country in terms of health care and Medicaid savings and quality of care for its constituents.

I would point out one fact—and I had the good fortune of serving the State legislature while Governor Chiles was Governor—one fact that Florida has the lowest percentage of seniors in nursing homes of any State in the country. Of 50 States in the country, we have the lowest percentage of seniors in nursing homes.

We also have the highest percentage of seniors of any State in the country, yet we have the lowest percentage of seniors in nursing homes, which is one of the reasons why we are 48th in expenditures of every State in the country in terms of Medicaid dollars. We have been successful.

We are the paradigm of community care for the elderly, a program which the State legislature funds to keep people out of the nursing homes and into community care. Those innovations are a success story.

Again, you don't have to be an MIT economist to understand we would be absolutely penalized by the types of proposals of the budget recommendation.

Mr. CHILES. First, I think maybe all of us have a plan—I will give you a copy of that—that I think would treat the growth factor in a more fair way. I think the gist of what this is about, I believe, is we are facing a terribly flawed system that we have now and everybody says we have got to blow it up.

I think what some of us are saying is if we are going to blow it up, let's don't put back in place a system that is flawed in itself from the outset. Let's at least be fair.

If we are going to save this $187 billion, let's treat States, let's treat the individuals in the States fairly Let's share the pain. Let's do in it a fair way. And let's don't lock in, don't say to everybody that every State is exactly the same that you can have a cookie cutter that you can treat Michigan and Florida the same way.

We are not the same, and just as the Governor of Michigan has said, Lansing is different from DePaul, or somewhere else, and certainly Florida and Michigan are different. So you have got to have that flexibility, and I think you have to recognize what States have done to reform their own system. If you are going to lock in a base year, at least treat us fairly in how you put that base year in.

Mr. DEUTSCH. Governor Engler.

Mr. ENGLER. I don't disagree with the idea of certainly everyone does have a different strategy. I just think you find everybody where you find them.

I mean, we are here because of the system that we have. We have all done it differently, if we could have designed this system back in 1965, or at any point, coming forward over the last 30 years. One thing that is not being said in terms of your observation about the budget, my understanding is you don't have any money down here, that you have a deficit and, therefore, you can't fund a current CBO baseline budget.

You won't pay us. And so you are going to reduce in one expense what they and those expenditures are by some amount. What we fear is they will continue to pass programs which might be able to keep all kinds of management controls and mandates in place and then reduce the money and tell the States to figure it out. That won't work.

Mr. BILIRAKIS. Forgive me, Governor.

Mr. DEUTSCH. Mr. Chairman, if I can just respond?

Mr. BILIRAKIS. We are running out of time, and I want to try to give everybody an opportunity. In fact, I would like to ask the remaining members, and forgive me for changing horses in the middle of a stream, if we can get down maybe to 3 minutes each, we might be able to get everybody in. I can't help, but I understand the Governors have to leave and so it is unfair—some people have been here from the beginning and probably won't even get an opportunity. So let's see, we are going to go on to Mr. Whitfield.

Mr. WHITFIELD. Thank you, Mr. Chairman.

I also would recommend that any of you interested in Medicaid read those issues in The Washington Post back in January and February 1994, because it does show very clearly that part of the problem is the liberalization of programs, and between 1984 and 1990, as Dr. Ganske mentioned, adopted 24 new initiatives in the Medicaid program that the first year all of them cost $888 million, by the 5th year, they cost $5.6 billion a year.

So in the true sense of being in politics, it is much easier to say yes to people and give to people, than it is to say we want to do this, but can this Nation and can these States afford to do it?

All of us, obviously, are concerned about poor people, about children, about disabled people, and we know that this program continues to expand. And it is no wonder that States are having difficulty with the increased expenditure, but is there any responsibility or is there any way that we can provide incentives either through

some sort of grant program or a tax incentive so that individuals would bear more responsibility themselves in taking out individual insurance to help on long-term care, because that is where the true cost is, and as we discuss block grants, giving money back to the States, and let you administer the programs, are any of you considering a program that would provide incentives for individuals?

Mr. CHILES. Yes, sir. We have a waiver now that we are hoping our legislature will adopt that allows us to take the savings that Florida is now generating because of putting people in managed care.

We will have 65 percent of our people in managed care. That is generating a lot of savings. The Federal Government under this waiver would allow us to take part of the Federal savings and match them with State savings and provide a coverage, a subsidized coverage to those people that are just above the poverty line, in which, depending on how much they are earning, they would pay part of the premium and we would pay part of the premium. We can insure about half our uninsured using those savings. So that is something innovative we are trying to do under our waiver.

You can put that inducement out there and people will buy it. We also have a CHPA program, cooperative purchasing for small business in Florida, and we are having a tremendous expansion on that by allowing small business just to be able to pool and purchase insurance at discounts, in effect like bigger companies. You can certainly have incentives like that out there.

Mr. WHITFIELD. I notice in Minnesota a family of four earning—a family earning $40,000, the children are covered under Medicaid. You can make an argument that they should bear some of this.

Mr. BILIRAKIS. The gentleman's time has expired. Thanks. Mrs. Lincoln.

Mrs. LINCOLN. I thank the chairman, and I am sorry to see that Governor Sundquist is gone because I am very much affected by TennCare in terms of the medical school in Memphis and the service it gives to my district in the eastern half of Arkansas.

As Governor Chiles mentioned, if we are going to blow up the system, we have to have something to replace it with. And many of you have suggested managed care as that replacement. In my experience with TennCare and the problems we have seen in terms of the lack of repayment to the providers and the length of time it has taken to reimburse them, and a whole host of other things, the Med center in Memphis has closed down now the burn trauma center and the AIDS center, and they are talking about closing down the OB-GYN department. They have reduced their services. They no longer serve people from eastern Arkansas at the medical school.

In light of that, I would like to ask you all about the details of replacing this out of control system, for I don't disagree that we have to reduce the increase in Federal Medicaid spending that we are currently seeing. Without a doubt, we have to reduce that. However, the degree to which you are talking about reducing it, I think, is devastating.

What are your solutions for providing special pediatric care to children that will be left unattended, especially in rural areas like

ours where we are using telemedicine to get to the remote areas? What will you do in regards to the medical schools? Right now the Med center in Memphis, having closed many of the divisions I previously mentioned, has also reduced by a tremendous amount its residency program. And in terms of keeping the quality of care in this Nation, what will happen to our medical schools and our training center?

And in light of the testimony, I know it was Mr. Edgar's, but some of you others have alluded to it, you argue the Federal mandates are forcing your States to pay for services you would probably not pay for if there were no Federal mandates. What are those services that you would eliminate?

Mr. LEAVITT. In the minute and a half that is remaining, obviously, we will not be able to answer all those questions, but a couple that caught my interest.

We are struggling now as to the future of our economic health center as to how to position it in the future. Medicaid has been a big part of subsidizing, in essence, research through a series of very complex cross subsidies that may make sense or may not. The point is, however, that there are going to be a lot of solutions that are attempted. A lot of them will work; some of them won't.

We will figure out which ones work quickly, because we have a financial incentive to do that, and which ones won't work quickly. I think the issue is whether or not you want to turn that complex set of questions over to one subcommittee in Congress or 50 laboratories of democracy, all of which will finds different solutions and different combinations of which will work.

Mrs. LINCOLN. What are your solutions for the special pediatric care and the medical schools? In the newspaper today, I read that TennCare was supposed to get matching funds using some State funds. They found they were county funds. They are not even State funds, they are county funds.

Mr. LEAVITT. Any moment I expect the chairman to say your time is up. I would be delighted to sit down and speak with you about this, because this is a dilemma that is very contemporary in our State and one in which we think we are coming up with a set of logical solutions. However, you may have some better solutions.

Mrs. LINCOLN. I do have two bills on children's health care and one on rural telemedicine.

Mr. LEAVITT. And I want to know about what they are. We get into complex issues dealing with antitrust, for example.

Mrs. LINCOLN. We do, too, and rural areas.

Mr. LEAVITT. And rural health care technology. All of this overlaps. Being able to contemplate this in a Medicaid bill, that doesn't make any sense. What makes sense is to be able to have the flexibility for a lot of people to be able to do things that will make sense. And if we have that flexibility, then when you figure it out, you can come and tell me, because I want to know. And if I figure out a piece of it, I will share it with you, and we will figure out a much better system than if it is a bill that thick and everybody has to go through a series of waivers that take 1½ years and you find one piece doesn't work and you have to go through a stack that big to get another waiver. Doesn't make sense.

Mr. BILIRAKIS. The gentlelady's time has expired. Thank you, sir. Forgive me for interrupting.

Mr. Burr.

Mr. BURR. Thank you, Mr. Chairman.

Let me commend all of you who are here today. I have a chart here showing the per capita expense by each State. Every Governor here today falls on the bottom half of that, meaning that we are doing some things right as it relates to the Medicaid coverage.

Governor Chiles, Florida has filed and received a waiver, if I understood you correctly. How long did that take?

Mr. CHILES. It took us about 7 to 8 months.

Mr. BURR. About 7 to 8 months.

Mr. CHILES. Yes.

Mr. BURR. Governor Leavitt, Utah filed for a waiver but has not received it?

Mr. LEAVITT. Yes.

Mr. BURR. How long has that been?

Mr. LEAVITT. We are in the 6th or 8th month. We have had waivers that had been approved that took a substantial amount of time. The most recent waiver we have applied for probably 4 or 5 months ago, so we are still a long ways from approval.

Mr. BURR. How much contact during the period of time of the approval process did HCFA have contact with individuals in your State?

Mr. LEAVITT. There are people to answer that question better than I, because, obviously, our health department handles the direct contact.

Mr. BURR. Okay. Governor Engler, what does HCFA bring currently to the Medicaid program?

Mr. ENGLER. Delay, cost, regulation, rules. Nothing in terms of quality of care.

Mr. BURR. Let me go to the States real quickly, Governor Engler. Are there currently States, and again looking at my chart we have a per capita expense on New Hampshire of 9,661 and Mississippi, 2,681. Are there States currently out there that when we change, when we blow up the system and we come back with a new one, are there States that should be cut on their reimbursement to start with?

Mr. ENGLER. We need to get away from the system that is driven the way this one has been driven. That is why the block grant approach has such appeal because it gets us to a more rational basis.

I think that States have made policy decisions to spend whatever they are spending now. And some would argue some are spending too much. Some would argue some are spending too little. They have worked that out in their political process and then they have used the system as it is designed. We need to get away from this. Some think 80 percent reimbursed, some say it gets 62 percent reimbursed. Et cetera.

I think the approach we use in the 1995 base year—we can enter into a dialog of where we go in the future, but I think what we are talking now is a system where the incentives finally are there for the States to be innovative, to save the time and delay that is represented by this paperwork, to get reforms and innovations to market.

Mr. BURR. Is the discrepancy that exists there, is that based upon differing coverages?

Mr. ENGLER. Sure.

Mr. BURR. Should we go to one standard coverage, that the Federal Government participates in reimbursement?

Mr. ENGLER. For 30 years you have not done that. I wouldn't suggest now is the time to start.

Mr. BURR. Governor Chiles, if we could solve the formula problem and the flexibility problem that you expressed, could you favor the block grant program?

Mr. CHILES. I probably would rather see the Federal Government continue to be a partner, because I think the Federal Government has some responsibility to children. But, now, yes, I want the flexibility. I want to see that. I think we can do it better in the States if we had the flexibility.

But I think part of the disparity now is not only in coverage but also is in cost. The cost of the procedures are much higher in some States than they are in the others.

You know, I think what you have to come to grips with in some States, if you are going to change this where there was a partnership, and where the Federal Government sort of hung money out as a carrot, if you will, do certain programs, you will get this funding. Now we are going to do away with that and say the Federal Government is going to give to the States *X* number of dollars to provide all of this health care, then you have to do that not on an old basis that you did on a matching thing, you have to do it on a fair basis that says children are entitled to a certain thing regardless of where they are. And if people move, the money should move with them. If you do it on that basis, you at least are sharing the pain.

Mr. BILIRAKIS. The gentleman's time has expired.

Mr. BURR. I yield back, Mr. Chairman.

Mr. BILIRAKIS. You will yield back what? Mr. Brown.

Mr. BROWN. Thank you, Mr. Chairman.

Recently I visited Health Hill Hospital in Cleveland. It is a children's hospital for very, very sick children. Eighty-five percent of the patients at Health Hill are Medicaid funded and they depend on Medicaid for their coverage not because these families are necessarily poor, many are middle-class families that are hit with very, very, very high medical bills because of traumatic and terrible diseases that their children have.

I guess, Governor Chiles, we will start with you. Would you support a minimum standard to ensure that those very sick vulnerable children have coverage and should they be carved out and protected that way; and also, should other beneficiaries, those that are disabled, the elderly, also be protected that way? Basically, should there be any of those strings attached to block grants?

Mr. CHILES. I would rather not have a lot of strings attached, but at some stage, having been a budgeteer at one time and sitting on the other side of the table, I don't think you ought to give Federal dollars without some kind of accountability or standards to the States of what you expect and how you expect those Federal dollars to be spent. That is why I worry that some States that receive benefits could take money out of this and put it into other programs.

That is happening in disproportionate share. We know that is happening in disproportionate share. It is totally unfair and now no one wants to do anything about it.

Let us don't create something else. So I think there has to be some requirements that you are going to follow the money, and there probably has to be some safety net that the Federal Government should say we are putting out there.

Mr. BROWN. Governor Engler, with the cuts in or the reduction in the increase, when over 70 percent of the growth is attributed to the cost of health inflation and the growth of the eligible population, do you carve out something to make sure that the most vulnerable under Medicaid, that the children that are the sickest or the disabled, are protected and that their services are not cut?

Mr. ENGLER. We would do that as a State. We would not suggest that you try to do it with the fine hand of the Federal Government. We think that we probably could do that more effectively at the State level.

The problem is that once you try to do that from Washington, it just does not work. Congressman Wyden earlier suggested some of the changes in Oregon. I mean, there might be some situations where we would decide that the investment in treatment should not be made. There are those profoundly difficult questions. I suspect if Mickey Mantle were a Medicaid patient in Oregon he would not be eligible for a liver transplant.

Mr. BILIRAKIS. The gentleman's time has expired. Mr. Bilbray.

Mr. BILBRAY. Thank you, Mr. Chairman.

I want to say to the Governors I appreciated your being here reminding those of us in Washington that Washington is not the only well of wisdom and compassion. As somebody who was operating these programs last year, I am quite interested in this issue and I think that the Governors here are reflecting the good parts of the States' administration.

California is going to have over almost 2.5 million people on managed care within 18 months. I would like to ask Governor Chiles, do you agree with Governor Wilson that the Federal Government must assure full fiscal responsibility for service to illegal aliens?

Mr. CHILES. Yes, I do, definitely.

Mr. BILBRAY. And because we are really trying to be aggressive on this in California, the other issue is do you agree with our Governor that the Federal funding baseline and growth rates established for block grants must reflect the realities in the States and not the arbitrary number that is being proposed right now?

Mr. CHILES. Absolutely.

Mr. BILBRAY. Okay. With that assumption that the block grants would be modified to reflect the realities and be distributed in a manner that reflects the realities, would you support my Governor's position, that the States are given full flexibility? Would you then support the block grant of Medicare and eliminate the individual entitlements at that time?

Mr. CHILES. I think it is going to happen. If I had my druthers, I would like to see the Federal Government still have some responsibility. I worry about what happens in a major recession. I worry about what happens there. I don't think the Federal Government

should be able to walk away from children and its responsibility to them.

I know there is going to be block grants. I want them to be done fairly.

Mr. BILBRAY. My concern, as somebody who managed a county of 2.6 million, was that a Federal bureaucrat did not seem to have more compassion and caring for the children of my county than I did or the people that lived in my county. And I would have to say to the Governor, I appreciate the fact that you point out to members that we are still talking about increases.

I live on the Mexican border, and I understand bilingualism. But now that I am a freshman here, I realize that we don't all speak English here. There is this Washingtonese that says that a 4 percent increase is a major slash-and-cut-and-burn proposal.

And no wonder the American people are confused. It would be much easier if we spoke in an authorized, officially recognized foreign language. Because the beltway does have its interesting terminologies and it sounds so much like English that those of us who have not picked up the nuances of Washingtonese do not understand how misguided it can be or misinterpreted.

Mr. CHILES. Congressman, I also would say that some of us that have been here and have been in the States also understand that a 4 percent growth does not mean an increase in a State like Florida or in a State like California, where you know your population is growing faster than that and where your kids that are coming in, your elders that are going. So, you know. I also know——

Mr. BILBRAY. But, also, the States are losing population.

Mr. CHILES. I understand that English, too.

Mr. BILIRAKIS. Thank you, Governor. The gentleman's time has expired. Mr. Pallone, very quickly, sir.

Mr. PALLONE. Thank you, Mr. Chairman.

My concern, and I will be brief, is that every, all the changes that are being proposed here are basically budget driven. In other words, that we are block granting Federal funds so that we can reduce the amount of money in our Federal budget.

The Governors want more flexibility so they can reduce the amount that they have to pay out to the hospitals. The hospitals will then, or the other long-term facilities, will simply reduce the amount of money they have to spend and so therefore quality of care suffers.

I guess part of the problem I have with all this is that I am concerned that actual costs incurred from Medicaid are not going to be reimbursed. In other words, there isn't going to be enough money because everybody is trying to save money. There will no longer be a real relationship for the cost of Medicaid services and what various levels of government are providing.

I mention that because, if I understand—I wasn't here earlier so you have to forgive me and correct me if I am wrong—I think many, if not all of the Governors, said they would like to see the Boren amendment repealed as part of this overall reform. And I don't really understand that because it seems to me, even if we do block grant or do some of these changes suggested, at least if we have the Boren amendment we have some sort of guaranteed reimbursement rates which will reflect actual costs. I would be opposed

to abolishing the Boren amendment for that reason, regardless of what changes are made here.

I just wanted to hear some of your comments about that. If you believe that this is not just budget driven, that we are trying to reimburse the actual costs, why would you be in favor of abolishing the Boren amendment?

Mr. LEAVITT. I have never seen or acknowledged the Federal courts to be a better determination of what actual costs were than the marketplace. The marketplace is much more well-attuned to actual cost than a Federal judge.

Mr. PALLONE. In other words, you are just concerned about the court's interpretation of the amendment. You don't have a problem with the amendment per se.

Mr. LEAVITT. I am concerned about the whole process of not allowing the marketplace to determine what those levels ought to be and having them arbitrarily set in a way that turns out to be quite capricious.

Mr. ENGLER. You unfairly regulated the States under the Boren amendment vis-a-vis all private carriers out there, where they all negotiate—when the UAW negotiates a contract for the auto companies and they go to a provider and say, what are you going to charge us for a procedure, what are you going to charge us for a night of hospital stay; they negotiate that. States are prohibited from doing that under Boren.

Mr. PALLONE. I guess what I don't understand is, without any kind of Federal standard that says your reimbursement rate has to be linked to actual costs incurred for Medicaid services, what guarantee do we have that if we block grant this money, that, for budgetary reasons, States are just not going to cut and establish a new rate that has no relationship to the actual cost of services.

Mr. ENGLER. It is a market basket. We are purchasing services. What is wrong with letting markets work? I thought that was the American way. We trust markets, right?

Mr. PALLONE. Yes, but if the State simply decides to provide less money, as in the case of my State, in New Jersey, then it seems to me that what happens is that the health care providers, the hospitals, the different facilities simply cut back on the services that are provided and don't provide the same level or quality of care.

Mr. BILIRAKIS. The gentleman's time has expired.

Mr. PALLONE. Thank you, Mr. Chairman.

Mr. BILIRAKIS. I should make a record of that, I guess. Mr. Norwood.

Mr. NORWOOD. Thank you, Mr. Chairman. As a previous provider of Medicaid, I need 3 hours, but I will do the 3 minutes. I will ask my questions fast and appreciate a short, fast answer.

Governor Chiles, I know distribution of funds is on your list. You have made that very clear. Appreciate it if you would submit your plan to this committee.

Mr. CHILES. Yes, sir.

Mr. NORWOOD. I would like to ask you to tell me that if we use Mr. Kasich's budget numbers, and that is all we are dealing with at this point, and we do block grant the money back to the States from Medicaid, will Florida get more money in 1996 than it did in 1995?

Mr. CHILES. I believe that the part of the way this is designed, and I think that is, under the budget resolution, kind of clever. You know, we are going to save the pain through the next election. So you are going to give us a little more in 1996, then you start——

Mr. NORWOOD. The answer is, yes, they are going to get more in 1996 than 1995?

Mr. CHILES. In actual dollars, yes.

Mr. NORWOOD. How about 1997? Will they get more in 1997 than in 1996?

Mr. CHILES. I think we still get more actual dollars, yes.

Mr. NORWOOD. You would probably debate that doesn't suit you? That isn't enough?

Mr. CHILES. No, I would debate that with the increased caseload that I have——

Mr. NORWOOD. You would say the 1996 amount doesn't suit you? That is not quite as much as you would like to have?

Mr. CHILES. I would say we will not have as much money to spend for people on Medicaid in 1996 or 1997 or 1998 or in 1999, in any of those States.

Mr. NORWOOD. But the government is going to send you an increased amount of dollars. Just not the amount you would wish to have.

Mr. CHILES. That is right.

Mr. NORWOOD. So the debate is about how much we increase our spending, not cuts. I don't want to belabor that, except to tell you that that is very confusing for the American people.

Mr. CHILES. Well, it is also, Congressman, just like the debate about, you know, your paycheck. You are going to get more dollars because you have a cost-of-living increase, but I don't think you consider that a raise. I didn't when I was here.

Mr. NORWOOD. Actually, I am not for that either, in a government that can't really afford it.

If you are able to manage Florida's Medicaid program through the block grant program, do you envision that Florida would set priorities in health care?

Mr. CHILES. Absolutely.

Mr. NORWOOD. Do you believe that perhaps the Federal Government cannot simply buy everything it wants to buy in health care? There has to be some intelligent guidelines as to what is available. Do you agree with that?

Mr. CHILES. Sure.

Mr. NORWOOD. The growth rate, I heard earlier, has averaged, in Medicaid, 15 percent a year. And this is for anybody. Does anyone know how much of that growth rate might be contributed to a Congress that has mandated increased services?

Mr. BILIRAKIS. Whoever answers that, please do it quickly.

Mr. NORWOOD. Just answer it.

Mr. ENGLER. It is partly that and partly restrictions on our ability to actually run the program. I mean it is a combination of factors. I think if we look at what the private sector has been able to successfully do in terms of bringing its costs down, some of those savings are potentially there for States as well.

Mr. CHILES. And it is partly that people from a lot of States are moving to Florida, and as they age, you know, they become Medicaid recipients.

Mr. NORWOOD. Not talking numbers here. I am talking about increased services. I know numbers is part of it, too, but I wondered what of that 15 percent had to do with increased mandated services on the States.

Mr. BILIRAKIS. The gentleman's time has expired. The gentleman from Connecticut, Mr. Franks.

Mr. FRANKS. Thank you, Mr. Chairman, and I, too, would like to welcome the Governors, and I will be very, very quick and brief.

My question deals solely with the poor, those individuals on welfare, and the issue would be population shifting. Without limited Federal oversight, how do we avoid the prospect of creating a true State that would be the new "welfare state"?

Because won't the individuals who are poor do some evaluation work themselves, and would look at the benefits in one State per AFDC, housing, health care, et cetera, and move to the newly created welfare state? And wouldn't each Governor strive to be what can be perceived as being the best from one person's perspective but obviously from another person's viewpoint the worst Governor in the country per se?

And, obviously, those States like mine, Connecticut, that are deemed as being more of the affluent States in the country, are very concerned about the prospects of people looking at our State, and possibly other States around the country, as being that type of State. And, yet, obviously, proposals can be put forth by respective Governors that would prevent that from happening, but there could be a big rush for all the Governors saying, I can do better than you. You are saying this; I am going to do this. You are saying this; I will do this.

Mr. ENGLER. That is the race to the bottom theory that has been talked about. I think it has to be discounted significantly. You know, rent plays a role, the cash benefit plays a role, all that stuff. I would rather look at the success we have had. We have had about 100,000 people move off of AFDC, and we hope that they will be able to continue to work and continue to have employment situations where they are going to be insured. That is the way to reduce the rolls, that is the way you help make more benefits available for those who need it.

Mr. FRANKS. So you are saying people will not make an evaluation of the benefits per each State and make a——

Mr. ENGLER. There is no evidence they have done that on the basis of cash welfare benefits in the Midwest.

Mr. FRANKS. Well, I would tell you that people on welfare have said to me; that is what they are going to do, being in one State versus—I am not saying that is not something we should not encourage, but without some limited Federal oversight, some minimum requirements, then we are looking at that prospect. That is my point.

Mr. LEAVITT. The State of Vermont currently has cash welfare benefits totaling $900, whereas the average would be somewhere in the neighborhood of 3 or 4, and you don't see any particular land

rush to Vermont. I think, as the Governor has suggested, that is highly overstated as an issue.

Mr. FRANKS. Governor Chiles?

Mr. CHILES. I would say that a heck of a lot of people come to Florida every year and we don't pay very much. So they are not coming for the welfare benefits.

Mr. ENGLER. They are Haitians and Cubans, though; aren't they?

Mr. CHILES. Not all.

Mr. BILBRAY. New Yorkers.

Mr. BILIRAKIS. The gentleman's time has expired. Mr. Hall, did you have anything, quickly, for these gentlemen?

Mr. HALL. No, thank you, Mr. Chairman.

Mr. BILIRAKIS. Well, gentlemen, I appreciate very much your taking the time to be here and staying as long as you have. I hope we have not messed up your schedules too badly. Thanks for all your assistance.

[Whereupon, at 12:15 p.m., the subcommittee was adjourned, to reconvene at the call of the Chair.]

[Additional material submitted for the record follows:]

PREPARED STATEMENT OF TOMMY G. THOMPSON, GOVERNOR, STATE OF WISCONSIN

Mr. Chairman and members of the subcommittee, most notably Congressman Klug from our great State, it is a pleasure to provide this statement in support of congressional efforts to block grant the Medicaid program to the states.

There is ample evidence for the need to turn Medicaid over to the states under a flexible block grant. Throughout the 1980's and early 1990's, states were confronted with a relentless avalanche of federal mandates, as well as with an unprecedented level of micro-management. The result has been unsustainable growth, an array of Byzantine, virtually unintelligible requirements, and the straight jacketing of progress and innovation.

Wisconsin is a prime example of why states—and not the federal government—are best equipped to take Medicaid into the 21st century. Through effective use of managed care and a variety of cost containment initiatives, Medicaid expenditure growth in Wisconsin has been consistently 33 to 50 percent below national Medicaid growth rates. This was done while keeping Wisconsin Medicaid coverage the broadest in the nation. In voluntary partnership with health maintenance organizations, community providers, and community-based organizations, we have significantly improved access to and quality of care for low-income women and children through the use of managed care. Further, we leverage private sector competition where ever possible to contain costs. As a result, our Medicaid administrative costs and staffing levels are among the lowest in the nation for any health insurer, public or private.

In order for the block grant approach to be successful, three basic principles must be followed in crafting a new, streamlined Title 19. First, Congress needs to provide states with a maximum degree of flexibility. Specifically, states need the ability to set their own policies with respect to eligibility, coverage, reimbursement, and managed care.

Second, the individual entitlement must end. The history of the last thirty years has taught us that open-ended entitlements merely create dependency, unwieldy bureaucracies, and an uncontrollable and indefensible tap on taxpayer dollars. Finally, the base year and annual growth rates in federal funding must be equitable to all states.

As a governor, my commitment to health care for the poor is clear and certain. However, as a governor I do not try to prove my commitments by throwing ever increasing amounts of taxpayer dollars at an already broken program. Working together, I am confident that we will be able to craft a block grant system that will provide states with the means to deliver health care to low-income populations while ensuring the responsible use of limited taxpayer dollars.

Thank you, Mr. Chairman.

PREPARED STATEMENT OF ROY ROMER, GOVERNOR, STATE OF COLORADO

Mr. Chairman and members of the committee, thank you for the opportunity to submit testimony on the critical issue of proposed changes in the Medicaid program.

As a governor, I have very mixed feelings about the changes in Medicaid this Congress is proposing. I have been a consistent participant in efforts to reduce the federal deficit. I believe that Medicaid must be considered along with all other federal programs as a possible source for savings as we seek to balance the budget. At the same time, I do not see a credible set of programmatic changes that can be put into place to reach the savings that you intend to achieve in Medicaid. I do not believe that poor and working families and people with disabilities should bear the full burden of efforts to balance the budget. Yet, so far as I can tell, that will be the primary result of many of the current congressional proposals.

As the former chairman of the National Governors' Association I had the opportunity to lead a discussion among my peers regarding health care reform. Just two short years ago we reached consensus that cost containment and universal coverage were key goals. Medicaid cuts run counter to both of these goals. Two years ago we spoke of the need to end cost shifting from the uninsured to the insured. Today's Medicaid cuts will increase costs for employers, employees, and sole proprietors.

I realize that universal coverage is no longer seriously being considered, but that does not mean we should take steps that we know will increase the number of uninsured. In my state, if it were not for Medicaid, 28% of the children would have no health insurance. In my state, Medicaid pays for 65% of nursing home days. In my state, Medicaid fills in the huge gaps in coverage left by Medicare for 45,000 people. In short: Medicaid is attempting to cover for the fact that this country has no health insurance policy, no longterm care policy, and incomplete coverage for the elderly. No wonder Medicaid costs are rising—like our schools, every year we ask this program to take on new responsibilities because there is no other place to turn.

I believe that Medicaid can be made a more efficient program. If we were to sit down and have a discussion about changes to make in this program, we could identify a number that would decrease Medicaid costs. Governors have repeatedly asked for more flexibility, and I believe flexibility can improve the efficiency of the program. However, the cuts this Congress seeks to make in Medicaid were developed for the purpose of balancing the budget. We cannot make those cuts without eliminating services or cutting people off of the program.

It is nonsense to imagine that the efficiencies created through a block grant will be sufficient to bring down program growth to 4% per year. My state has one of the highest rates of HMO enrollment in the country and we have been aggressive in contracting with these HMOs to serve Medicaid clients. Savings of the size being discussed cannot be generated by relying upon managed care.

If this Congress is not willing to make concrete decisions about which populations it no longer wishes to serve, those decisions will be forced upon governors and state legislatures. We will have to choose between serving our children and serving our elders. We will have to choose between funding our schools and paying for needed health care. And, of course, we will make these decisions with fewer federal resources than we have had in the past.

I am prepared to roll up my sleeves and solve this country's deficit problem. I would like to do that in partnership with the federal government because I believe we need to address this issue as a nation. If the federal policy is block grants combined with substantial cuts, the federal government will have walked away from the problem, rather than grappled with it and solved it.

Let me emphasize the importance of the state-federal partnership in addressing issues like providing health care to our citizens. Federal participation ensures that states can withstand the effects of regional economic downturns. Our partnership directs resources to states with large elderly and disabled populations so that funds remain available in those states to educate their children. By contrast, block grants shift all of the risk of rising health care costs to the states. While we all agree that the terms of the state-federal relationship need to be revised, I urge you not to walk away from this partnership.

I strongly encourage this committee to do the hard work of reexamining the Medicaid program and the consequences of the cuts that are proposed. I encourage this committee to struggle with the issues that you may soon force upon governors. If there is a better way to deliver needed health care services to low and moderate income Americans while reducing the federal deficit, let us design that system together.

One of the stated objectives of balancing the federal budget is to reduce the burden our children will bear. If we leave our children unhealthy, without prenatal

care, and in a struggle over limited resources against their more politically powerful grandparents, we have done them no favors.

Again, I thank you for the opportunity to present this testimony to the committee.

PREPARED STATEMENT OF PETE WILSON, GOVERNOR, STATE OF CALIFORNIA

Mr. Chairman and members of the Subcommittee, thank you for the opportunity to submit testimony on one of the most compelling topics of the day: how the federal government and the states can work together to provide an effective and efficient medical safety net for the country's low-income and disabled populations.

I applaud the leadership of the House and this committee for their willingness to tackle this very difficult issue and for their inclusion of Governors in this historic debate. The House has actively sought the comments of Governors and Medicaid directors. This has been an important and productive dialogue; I look forward to it continuing throughout the legislative process.

Medicaid has become known as the "Pac-Man of State budgets" due to its exponential growth in recent years. The general fund cost of California's Medicaid program, for example, has grown from roughly $4 billion in state fiscal year 1990-91 to over $6 billion in 1994-95. In the absence of program reform at the federal level, state Medicaid spending will grow to an estimated $10 billion by 1999-2000, consuming scarce state resources and limiting funds available for other priorities.

The truly unfortunate fact is, this exponential growth has not yielded a great improvement in the provision of quality, accessible health care to low-income and disabled populations. Medicaid is an example of an entitlement program in dire need of reform. Turning Medicaid into a block grant to states is a proposal whose time has come and is one of the potential solutions that must be given active consideration.

A Medicaid block grant, properly and equitably structured, offers considerable promise in meeting two important state imperatives. First, a block grant would give states the opportunity to structure programs in innovative ways that reflect the specific needs of low-income populations, state priorities, and fiscal realities. States around the nation are bursting with good ideas for reforming their Medicaid programs in an effort to improve quality and access and to contain costs. The costly, time-consuming federal waiver process has not provided states with the flexibility they need.

Second, a block grant would give states the opportunity to get out from under the budgetary havoc and federal micromanagement that characterize Medicaid as currently structured. Legislative, regulatory and judicial mandates at the federal level have expanded eligibility, provider reimbursement levels, and benefits creating substantial and often unpredictable cost growth in Medicaid—and creating major budget problems for states.

In addition, the federal Health Care Financing Administration's "one-size-fits-all" mentality towards regulations does not reflect the diversity of state needs and circumstances across the nation, or within a particular state, and has created a rigid, inflexible and categorical system driven more by bureaucratic whim than rational program administration. Medicaid's rigid program structure and the laborious and costly process required to obtain federal waivers have stymied States in their efforts to achieve program innovation.

During the debate on this and other block grants, governors have been accused of lacking compassion for the welfare of our nation's children. In California, we have an excellent example of how it is the current Medicaid system, with its cumbersome federal laws and regulations, that lacks compassion as it stands in the way of the State's innovative efforts to extend vital benefits to uninsured low-income children.

In California, thousands of working families with children under 5 years of age cannot afford health insurance for their children. As a result, these children often go without the primary and preventive care they need. Their only contact with the health care system is through an emergency room.

To assist these children, I have designated $100 million in the State budget which, if matched by federal funds, could provide primary and preventive care to California's 600,000 uninsured low-income children under age 5. However, under the current Medicaid program, states cannot receive matching funds unless a comprehensive benefits package is provided—with a price tag of $400 million.

The result, California will be forced to either apply for a waiver, which could take over one year to receive and is subject to judicial review, or use the available state funds to provide benefits to only a limited number of children.

The federal government should be making it easier, not harder, for states to help children in need.

In short, a Medicaid block grant has the potential of not only bringing heretofore unknown fiscal discipline to a program now growing beyond federal and state government's ability to pay, but unleashing state innovation and creativity to improve the delivery and quality of health care for our most vulnerable citizens.

As you fashion a Medicaid block grant for the states, it is imperative that it be programmatically and financially structured to give states equal opportunity to manage successfully a slower-growing program.

First, block grants must be truly free of unnecessary federal strings and requirements. If the future growth of federal Medicaid payments to states is limited to an average of about 5 percent, as is suggested by the House Budget Committee, states must be given sufficient flexibility to lower program growth. There, of course, must be accountability. However, states must have broad flexibility to establish benefits, provider reimbursement levels, delivery systems, and, most importantly, eligibility. "Set-asides" that target priority populations could be acceptable, if they are appropriately structured to maximize state flexibility to provide care consistent with state priorities. The key requirement of state flexibility, nevertheless, is that the individual entitlement to services that is now in place must be eliminated.

Second, the federal funding baseline and growth rates established by a block grant must reflect the different realities and circumstances faced by different states. A federal baseline that freezes in place today's federal contributions would penalize states like California that have already reduced costs and have historically been disadvantaged by inequitable matching ratios. Further, a flat growth rate adjustment does not equitably account for the disparate program experience across states.

To ensure funding equity, the baseline established must include a reasonable "equity" adjustment for states like California to ensure that we are not permanently locked into a funding disadvantage. Further, the growth rate must be established to give states an equal opportunity to meet the financial targets set by the federal government. In particular, severity of care, caseload, growth, and the number of elderly in the state, all of which states have limited ability to curtail, should be accounted for in any growth formula.

Third, block grant must reflect the exclusive responsibility of the federal government for the costs of providing health care to illegal aliens. The idea of simply eliminating the OBRA '86 mandate on states to provide emergency services to illegal aliens, without making provision for the costs of care provided by hospitals and physicians, is unacceptable and would shift the obligation to cover illegal aliens to states and health care providers. The federal government must assume full financial responsibility for the emergency care needs of illegal aliens through establishing a direct billing mechanism between the federal government and the provider of services rendered to illegal immigrants.

While the prospect of a Medicaid block grant engenders several concerns and cautions, it cannot be emphasized enough that the current Medicaid system is falling short of meeting the needs of both beneficiaries and taxpayers. Federal policies have yielded a program incapable of effectively meeting the medical needs of low-income and disabled persons in a cost-efficient manner, and have locked in very obvious inequities between states.

Neither taxpayers nor beneficiaries can afford for the current Medicaid system to continue. If provided flexible and equitable block grants, states can develop new systems, based on local needs and resources, that will provide access to quality health care to the nation's most vulnerable populations, and keep cost growth in check.

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C-27. SHORT-TERM MEDICAID POLICY

27.1 Preface

The nation's Governors recognize that rapidly escalating health care costs in the face of the increasing need for health care access is the essence of the health care crisis that confronts our nation. The Governors are also aware of the varied and complex factors that must be dealt with if we are to achieve a solution to this crisis.

Currently, thirty-one states are struggling with budget shortfalls. A significant part of the fiscal pressure on states is coming from increased costs in the Medicaid program. In 1980, Medicaid spending accounted for 9 percent of states' budgets; in 1990, it accounted for nearly 14 percent of all state spending.

The increased costs of Medicaid not only represent the generally inflated cost of health care experienced by all purchasers, but are exacerbated by four years of Medicaid mandates.

States must have some immediate relief from the real and pressing problems presented by the Medicaid program if they are to move forward on long-term solutions. Therefore, the Governors call on Congress and the administration to work with us to immediately make the following changes to the Medicaid program.

- **Congress should delay the mandated implementation of the 1990 Medicaid mandates for two years.** This will give federal and state governments time to assess the depth of the recession and the opportunity to develop long-term solutions for the restructuring of the Medicaid program. Accountability based upon results is a better test of state performance than strict compliance with mandated procedures. In return for flexibility, the Governors seek to work with the administration and Congress to develop state-specific mutually acceptable agreements to measure accountability.
- **States must not be expected to implement any Medicaid program changes until the Health Care Financing Administration (HCFA) has published final regulations to guide program administration.**
- **States must be allowed to maintain their complete authority to raise funds to match federal Medicaid dollars without restriction from the federal government.**
- **To promote cost control and efficiency, states should be encouraged to continue innovations in provider payment methods.** Though Medicare and most private payers have moved away from cost based reimbursement, federal legislation has mandated that certain Medicaid providers be paid on the basis of costs. In operating our Medicaid programs, states should not be denied cost control options available to the federal government in operating the Medicare program.

In addition, with respect to three particularly troublesome mandates over the last four years, the Governors call upon Congress and the administration to make the following specific, programmatic changes.

27.2 Qualified Medicare Beneficiaries (QMB's)

Congress should assume full financial responsibility for all low-income Medicare beneficiaries who are not otherwise Medicaid-eligible. Since the passage of the Medicare catastrophic legislation in 1988, the federal government has increasingly passed on to the states the responsibility to protect low-income Medicare beneficiaries.

27.3 Nursing Home Reform

States should be considered in compliance with the law if a comparable quality assurance program is in place or developed. In the Omnibus Reconciliation Act of 1987, Congress mandated extensive new quality assurance measures for the Medicaid nursing home program. The statutory language permits limited state flexibility and puts Congress in the position of micro-managing the program.

27.4 Early Periodic Screening, Diagnosis, and Treatment (EPSDT)

In "technical" amendments to the EPSDT program legislated in 1989, Congress added major costs to this program. Therefore, the Governors propose two technical amendments to the 1989 law to:

- **With regard to screening services, clarify that states have the authority to specify qualified screening providers and that states are permitted to insist that such a provider can be required to provide all screening services.**
- **Give states the authority to provide only those services identified in a screen that are currently offered in a state's Medicaid program.**

While these changes clearly will not resolve the nation's long-term struggle to restructure the Medicaid program, they will provide immediate and sensible relief in dire economic times. These changes also would mark the beginning of a new and real partnership between the federal government and state governments over the design and implementation of the Medicaid program.

NATIONAL GOVERNORS' ASSOCIATION

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Governor of Iowa
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August 1, 1989

Dear Member of Congress:

Today the nation's Governors took action calling on Congress and the White House to adopt a two year freese on the enactment of further Medicaid mandates. Our Resolution was based on our increasing concern with the impact of the last three years of Medicaid mandates on our budgets, and, consequently, on our ability to properly fund education and other important services.

The Governors continue to support state options to assure Medicaid eligibility to our most vulnerable populations. Moreover, we are keenly aware that 37 million Americans remain uninsured. Consequently, we believe now is the time to debate solutions to our national health care crisis that accomodate both access to quality health care for all Americans and the need to control spiraling health care costs.

The Governors propose to use the two-year freese to work with Congress and the White House on a bipartisan basis, as we did on welfare reform, to find the best solutions to the health care crisis that confronts this nation.

Sincerely,

Terry E. Branstad
CHAIRMAN
IOWA

Richard F. Celeste
OHIO

Bill Clinton
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SUSPENSION

RESOLUTION* ON HEALTH CARE
(Proposed by the Committee on Human Resources)

BE IT RESOLVED, that the nation's Governors call on Congress and the White House not to enact any Medicaid mandates for a period of two years. Recent Medicaid mandates have put great stress on state budgets and undermined the states' ability to properly fund education and other important services.

Governors recognize that there is an urgent need to ensure the availability and quality of health care for all of our citizens, as well as to control health care costs. There are currently more than 37 million Americans – most of them working families and children – without access to basic health care.

The accelerating costs of Medicaid, Medicare, and other health programs argue for a new look at health care financing options, including federalization of Medicaid or an aggressive effort to restructure the system.

Therefore, the Governors propose to use the two-year freeze to work with Congress and the White House on a bipartisan basis, as we did on welfare reform, to find the best solutions to stem escalating costs while ensuring access to needed health care services for all Americans.

* based upon Policy C-5

AUGUST 1, 1989

TRANSFORMATION OF THE MEDICAID PROGRAM

THURSDAY, JUNE 15, 1995

HOUSE OF REPRESENTATIVES
COMMITTEE ON COMMERCE,
SUBCOMMITTEE ON HEALTH AND ENVIRONMENT,
Washington, DC.

The subcommittee met, pursuant to notice, at 10:30 a.m., in room 2322, Rayburn House Office Building, Hon. Michael Bilirakis (chairman) presiding.

Members present: Representatives Bilirakis, Hastert, Stearns, Klug, Franks, Greenwood, Burr, Whitfield, Ganske, Norwood, Coburn, Bliley (ex officio), Waxman, Stupak, Wyden, Bryant, Towns and Pallone.

Staff present: Melody J. Harned, majority counsel; Mary M. McGrane, majority counsel; Howard Cohen, majority counsel; and Kay Holcombe, minority professional staff member.

Mr. BILIRAKIS. The hearing will come to order.

I am pleased to convene today's hearing on the Vaccines For Children Program. The VFC Program was enacted, as you know, into law as part of the Omnibus Budget Reconciliation Act of 1993. Its purpose is to improve childhood immunization rates especially among children under age 2. It was designed to achieve this goal by making federally purchased vaccines available free-of-charge to eligible children.

Under the new program, eligible children are entitled to receive pediatric immunizations without charge for the vaccines that are used. States are entitled to receive pediatric vaccines purchased by the Federal Government for federally eligible children up to age 18. Program registered providers are entitled to receive the pediatric vaccines from States at no charge.

Eligible children are those that are Medicaid eligible, American Indian or Alaska Native, children whose health insurance does not cover the cost of vaccines and who receive immunizations at federally qualified health centers or rural health clinics.

Since its inception, serious questions have been raised about the effectiveness of this program. I believe the goals of the VFC Program are certainly laudable. Everyone is interested in seeing that every child is vaccinated. However, we must be sure—we must look into the program and make sure that it is the appropriate way to reach that goal.

There are still issues which need to be reexamined by Congress. These issues include the effectiveness of the VFC Program, the lack of accountability, and the disincentives within the program to de-

velop new vaccines for children. In fact, participants in our third panel are experts on the issue of vaccine research and development and will discuss this particular issue in great detail.

We will explore these issues and others during our hearing today, and I would like to thank our witnesses in advance for taking time out of their busy schedules to testify before the subcommittee and, of course, look forward to hearing their testimony. Thank you.

And I want to recognize other members for their opening statements, and would now yield to Mr. Waxman.

Mr WAXMAN. Thank you, Mr. Chairman.

I am pleased that we have an opportunity to look at the Vaccines For Children Program today and to consider the impact on that program and the children who it is designed to serve if it is subsumed within a block grant of the Medicaid Program.

In our opening hearing on the Republican budget proposal to severely reduce spending on Medicaid and cap the program at a no strings block grant, we heard of the severe financial problems that will be faced by many of our States, yours and mine, particularly, Mr. Chairman, because of problems with the distribution of the funds.

We saw projections of the numbers of beneficiaries who are likely to lose their assurance of coverage if the growth rate of Federal funds is held to the level of 4 percent or below. We began to sense the intensive warfare that will ensue for the limited Medicaid dollars between children and the elderly, between providers of preventive care and nursing home care, between severely disabled children and needy seniors.

Fewer children will be covered in State Medicaid programs, and certainly we will stop our progress toward Medicaid coverage for all children below poverty. Surely if this vaccine program disappears into an inadequately funded block grant, less money will be spent on vaccines and fewer poor, uninsured and underinsured children will have the costs of their vaccines covered.

With the severe pressure discretionary funding will be under in this budget and in future years, there will be no replacing these funds with any increase in support for the CDC vaccine program, and what funds CDC now has to help the States support outreach activities will disappear in an effort to try to mitigate the loss of the Vaccines For Children Program.

Mr. Chairman, we have many differences on this subcommittee, but surely we all share the goal of achieving the highest possible immunization rate for our children.

Today we will hear from the American Academy of Pediatrics, the Association of State and Territorial Health Officers, and the Children's Defense Fund that maintaining a strong Federal focus on immunizations is essential to this goal. These groups represent doctors and health officials who see children in their offices and clinics every day. They know how much easier and less costly it is to prevent measles, pertussis, polio and other preventable diseases than it is to treat these illnesses and serious complications that can result from them.

These witnesses are advocates, not for big government or more spending, not for interference with State flexibility, but for chil-

dren. I think we should listen closely to what they tell us about this program and the children it serves.

I recognize we will hear some criticism of the implementation of the Vaccines For Children Program and concern about the milestones that have not been met, but let's remember that this is a program that has been in place for less than 9 months. Many States, in fact most of them, have made very effective use of the funds made available through the VFC, and the others are well on their way.

More to the point, this progress will be lost, and we will actually move backward in our commitment to immunizations if we proceed with plans to eliminate this program by wrapping it inside a Medicaid block grant. We will face many tragedies if we turn our back on the Federal commitment to provide coverage to the needy and vulnerable among us. Nowhere will this be more short-sighted than in the case of our children, and nowhere will it be more counterproductive than in the provision of immunizations for those children.

Thank you, Mr. Chairman.

Mr. BILIRAKIS. I thank the ranking member.

Mr. Bliley.

Mr. BLILEY. Thank you, Mr. Chairman. I commend you for holding this hearing on the implementation of the Vaccines For Children Program. A serious look at the goals, implementation, and success of this program is long overdue. The program has been troubled since its inception.

I would like to take just a minute to review some of the highlights of this program. It began on February 12, 1993, with an announcement by President and Mrs. Clinton of their first major domestic policy proposal, the Childhood Immunization Initiative to ensure that all children are immunized by their second birthday. Much of the President's remarks on the subject were directed to the unconscionable costs of vaccines and an attack on drug policies in general.

President Clinton stated, "We will make sure that excessive profits do not stand in the way of children's health."

I think perhaps the best description of the flaws in the administration's proposal were made by Senator Dale Bumpers, long regarded as the most knowledgeable member of the Congress on immunization issues. In a Dear Colleague letter he distributed before the program was enacted into law, he stated: "First and most important, the proposal assumed that vaccine cost is a significant contributing factor to our Nation's low immunization rate. This is simply not the case. As the government's own research tells us, the real culprits are more complex and more difficult to address. They include lack of sufficient public education about the need for full immunization, compliancy of parents toward fully immunizing their preschool children, and failures of providers in the public and private sectors to use all available opportunities to immunize their preschool age patients."

Over 97 percent of all children are fully immunized by the age of 5 when they begin school. Children enrolled in Head Start and licensed day care enjoy immunization rates of over 94 percent. This success is not a function of Federal and State spending, rather it

is a clear function of State laws that require full immunization as a condition of enrollment.

Even for those that assume that immunization costs are a factor, the provisions do not cover the fees charged by physicians for administering vaccines. A recent study published by Brandeis University found that over 64 percent of the total cost of immunizations is for physician fees. In light of these fees, it is evident that eliminating vaccine costs would not reduce cost barriers in any significant way.

Unfortunately, the warnings of Senator Bumpers and others were ignored, and the program became law. Testimony GAO will present today simply illustrates the accuracy of these warnings. This chart is simply one example. It depicts the 17 counties in the United States which reported measle cases every year in the period 1980 to 1989; as the GAO will point out, the problem of delayed immunization is concentrated in a small group of geographic areas, areas which could be efficiently targeted to improve immunization.

Yet, the Vaccines For Children Program does almost precisely the opposite. It makes a grandiose and failed attempt to take over the purchase and distribution of almost all vaccines with little regard to the true needs of unimmunized children.

I look forward to the testimony of our witnesses today, Mr. Chairman, and yield back the balance of my time.

[The chart referred to follows:]

GAO The 17 U.S. Counties Reporting Measles Every Year 1980-89

Mr. BILIRAKIS. I thank the chairman.

Mr. Wyden.

Mr. WYDEN. Thank you very much, Mr. Chairman.

The General Accounting Office report issued today presents some very troubling findings concerning the management of this program. As both a strong supporter of Federal efforts to immunize America's youngsters and as a requester of the GAO audit with Congressman Klug and Senator Bumpers, I believe the report's findings can neither be dismissed nor mitigated as merely poor analysis based on bum data.

This project has problems. They go to the core of efforts to combat a major public health problem. Without an aggressive bipartisan effort to tackle the management problems in this program, the GAO report issued today is going to stand as an excuse to tear the heart and sole out of a critical national effort to immunize America's poorest youngsters.

Critics of a Federal role in vaccinating America's children are going to argue that the GAO has found that this is a program looking for a problem. I am struck by the report comment, "The evidence is not sufficient to conclude that the cost of vaccine for parents has been a major barrier to children's timely immunization." If that is the case, this Congress must ask whether the discount price forced on vaccine manufacturers for a health majority of their products sold in this country is going to have a long-term negative impact on the ability of companies to do research and development on new vaccines.

The GAO has concluded that as much as 30 to 40 percent of the real under-immunization problem could probably be done away with if practitioners only gave shots during the appropriate scheduled office visit for an individual youngster. In addition, the auditors note, the cost of the vaccine when combined with the additional costs associated with the doctor's visit represent only about 20 percent of the average vaccination bill.

I continue to believe that there is a place for a strong program which assists poor children with securing vaccines. However, it is apparent that attacking under-immunization rates may be a more complex problem than the VFC program, as now structured, is prepared to solve.

Now this audit raises additional serious concerns. The report estimates that something on the order of $45 million out of a program cost of $412 million goes to management and operation functions alone. That is a goodly chunk of money. Therefore, it is doubly frustrating to read GAO's critical evaluation of software tracking programs which program participants report as being virtually unusable.

Finally, it is disturbing to learn that GAO found that the accountability systems for detecting waste, fraud and abuse have largely been sidetracked.

Let me close, Mr. Chairman, by saying that I know that there are those at the Centers for Disease Control who have serious questions about the GAO findings. I hope that they can give us reasonable answers to the issues raised by this report because this report says that the current vaccines program is a prescription for a policy in political failure.

I think if we work together and work together constructively, we can cancel that prescription, make sure that the youngsters of America get the vaccines they need, and I look forward to working with my colleagues on both sides of the aisle in that effort.

Mr. BILIRAKIS. Thank you, Mr. Wyden.

Mr. Klug.

Mr. KLUG. Thank you, Mr. Chairman. I want to thank my colleague from Oregon. It was virtually the day this program got announced that he and I and Senator Bumpers and Senator Danforth from Missouri first raised questions about whether it would work or not.

Mr. Waxman said two things I want to elaborate on. First of all was the idea of the goal of immunization, and I don't think there is a single person on either side of this panel that disagrees with that goal. It is clear that there continue to be some absolutely perplexing and frustrating problems with low vaccination rates in a number of areas of this country. If you look here, for example, there are clearly defined 17 counties that continue to have measles epidemics despite the best efforts of Congress and local governments for nearly 10 years.

In the State of Wisconsin, for example, in Milwaukee, the immunization rate among 2-year-olds is only at about 35 percent. But, as we have said for the last several years—and Mr. Waxman said that we should listen very closely to what is going to be said today—the fact of the matter is, people who are running this program should have listened very carefully several years ago, because we said it wouldn't work and it hasn't worked.

The first and foremost problem is, and a number of my colleagues have pointed to this already, that cost is not the barrier which is preventing children from being immunized. In Milwaukee several years ago there was a measles epidemic where 98 percent of the children who developed measles already had access to both public health clinics and to Medicaid. The problem obviously had to do with access and parental responsibility.

If we were to listen carefully several years ago, we would have seen that 13 States already distributed free vaccines to every child in their State, and their immunization rates, frankly, were not all that different from the other States that had a mixed approach, as Wisconsin did, where kids who needed help got help, and kids who had insurance got covered by insurance.

Finally, I am intrigued to discover that the CDC has four unpublished studies which the General Accounting Office discovered that say the exact same thing: while CDC was arguing for this program on the one hand, its own research was showing that it was absolutely unnecessary.

The program, as you know, has grown 400 percent over the last 2 years. Its budget will approach more than $1 billion by 1997. I think very clearly what we want to do on this committee is to figure out how to solve the real problem. The real way to do it, as my State health department suggests, is to address the four problems they identified.

Clinics are not open at night or on weekends. Money is not available for outreach. The Federal Government has chosen to purchase more vaccines than to put money into outreach; in fact, in many

cases, has purchased more vaccine than the individual States can use. Finally, they need more money for education for missed opportunities with parents, and they also need more money for missed opportunities with physicians.

So I think we are all on this committee committed to spending money on child immunization programs, but let's give the flexibility to the States, as we said several years ago. Allow them to purchase more vaccines, allow them to keep public health centers open later at night, hire more public health nurses, hire vans to drive around neighborhoods, or spend more money on education.

I think, if a single incident characterizes the entire attitude of this program, it is the amazing decision several years ago by the Center for Disease Control to have the Nation's immunization programs' vaccines stored at a government warehouse in New Jersey.

Let me quote from an earlier GAO report: "The Federal Government has no experience with storing, packaging and delivering vaccines, and the GSA's warehouse currently handles 5,000 commodities, including office products, paper, hardware tools, paint solvents and adhesives. Fortunately, we eventually forced the termination of that project, but after we spent nearly three-quarters of a million dollars establishing it." I think that is an apt metaphor for the description of what we are about to face today.

All of us want to see an effective program that spends money intelligently, but as the GAO report, I think, strongly suggests today, the way this program is designed today is not an intelligent way to spend money.

Thank you, Mr. Chairman.

Mr. BILIRAKIS. I thank the gentleman.

Mr. Stupak.

Mr. STUPAK. Thank you, Mr. Chairman, and thank you for holding these hearings on the Vaccines For Children Program.

There are almost 50,000 children under the age of 5 in the First Congressional District of Michigan, and this program is vitally important to the children in Northern Michigan. In 1993, there were more than 2.8 million uninsured children under the age of 6 in this country. Nationally, 16.5 percent of the people in rural areas are uninsured. In my district, that is 14,000 children alone.

I believe that cost is a barrier to the parents of these children. Vaccines are expensive and many families can't afford to vaccinate their children. The cost of a full series of vaccines has increased from $27 in 1983 to $265 today. That is why the program is vital for the health of our children. Without this program, I believe many children will go without being immunized.

This program is particularly important to rural areas where public health offices are spread out over large geographic areas. I have six public health offices in just the upper peninsula of Michigan, which is the northern half of my district. It might sounds like a lot, but still I have families that have to go more than an hour to try to get to one of these public health clinics.

Having the vaccines available at the family doctor's office is more convenient in rural areas, and it makes it more likely that uninsured children will get the vaccines they need. The Governor of Michigan supports this program and, according to Michigan De-

partment of Public Health, the State of Michigan saves more than $1.6 million per year under this program.

Mr. Chairman, and I encourage all my colleagues to support this program because I believe it is an investment in our children's well-being.

Thank you, Mr. Chairman, and I yield back the balance of my time.

Mr. BILIRAKIS. I thank the gentleman.

Mr. Greenwood.

Mr. GREENWOOD. Mr. Coburn's turn.

Mr. BILIRAKIS. All right. Dr. Coburn.

Mr. COBURN. Thank you, Mr. Chairman.

I just wanted to make a few short comments about this. As Mr. Klug has stated, everyone has the children's best interest in mind. But as I look at the VFC Program, I see government regulation and a program resulting from government regulation in a previous government program. In fact, if you look in my State for the reasons why children are not immunized, it has nothing to do with the availability of vaccine, it has nothing to do with the dollars that the vaccine costs. It has to do with poor parenting and the lack of compliance of parenting in terms of what is best for their children.

The statistics show that with the epidemics that have been in this country, especially in regards to rubella and in rubeola, I believe, you will find that all of those, the vast majority, greater than 95 percent of those that contracted the disease were underimmunized not because they didn't have money, not because it wasn't available, but because the parent wasn't responsible for their child. We cannot throw a government program to solve that in this way.

The other thing that I think that we need to recognize—and I think Mr. Wyden has a great idea—we need to throw away this prescription. We need not to refill it, but we do need to offer and make sure that the are the funds available for those who are not getting a vaccination today because of the fact that there is an inhibitor that we can do something about.

But the most important thing we can do is recognize those things that we can't do anything about as a Federal Government and the things that can be most well accomplished at a local or at a State level.

I want to give you an example, in my practice in immunizing children, the VFC Program in Oklahoma has added 45 minutes to each office visit and 25 pieces of paper for a complete set of vaccinations from a newborn to a 2-year-old. I have generated that paper for Mr. Klug before so that he could see what we actually went through.

If you look at how the vaccines are shipped now, compared to how we used to buy them directly from the manufacturer, you will see government waste and money that is spent that is totally unnecessary. So I would, again, comment that this is a program that came about because of a previous government program and the ineptitudes and inadequacies of that government program. We should send this to the States, to the localities, with the flexibility and the money to accomplish what they need to do and get the Federal Government out of it.

Mr. BILIRAKIS. The gentleman's time has expired.

Mr. Towns.

Mr. TOWNS. Thank you very much, Mr. Chairman. Let me also thank you for having this hearing.

I am sorry to say that the Vaccines For Children Program is not really the right program to address our immunization problems. This is because the VFC Program fails to focus on the real barriers to immunization, particularly those facing innercity children and other hard to reach populations.

The United States' most serious immunization problems are in our poor areas. So, outreach is very important. Let me give you an example. The rates for 2-year-olds in some areas of the Bronx are as low as 11 percent. This is not surprising when you consider that at least in one instance in New York, when a mother whose child was eligible for Medicaid tried to get that child immunized, 16 out of the 17 doctors who are participants in the VFC Program refused to even schedule an appointment for the family.

Clearly the VFC Program is doing very little to improve these urban immunization rates. Instead of focusing on needed improvements in the delivery system including parent education, outreach, expanded clinic hours, and tracking, the VFC Program puts the bulk of resources into the purchase of additional free vaccines, even for those who can afford them and do not need to be assisted.

According to a recent article in the Journal of the American Medical Association and a wide range of public health experts, further provision of free vaccines is unlikely to make a significant impact in poor urban populations. Adequate supplies of free vaccines have always been available in public health clinics. The problem is getting those vaccines to children most in need.

It would seem to me that the $800 million we would have to commit to free vaccines in fiscal year 1996 could be better utilized on outreach and education services to parents, opening new clinics and implementing tracking systems to identify children who are behind in their immunizations. Now is the time to act and to refocus our immunization policies.

Mr. Chairman, I look forward to working with you and to accomplishing this goal because what we are doing now is just not working.

Mr. BILIRAKIS. I thank the gentleman. I certainly thank him for his concern.

Mr. Greenwood.

Mr. GREENWOOD. Thank you, Mr. Chairman.

Twenty-six months ago, April 21, 1993, members of the Health and Environment Subcommittee joined the members of the Senate Labor and Human Resources Committee to hear the Secretary of HHS, Donna Shalala, unveil the administration's Comprehensive Child Immunization Proposal.

The Secretary unveiled the President's universal purchase plan that would ensure that all children, including mine, would have access to a new entitlement program guaranteeing them government purchased vaccines free of charge.

I would like to take a moment to share with some of my colleagues who were not on the committee at the time a few of Secretary Shalala's comments. "American families are getting

squeezed by the skyrocketing price of vaccines." "The high price of vaccines is a significant financial barrier to obtaining vaccinations for preschool children." "Our plan will eliminate financial barriers that impede the timely vaccination of children and facilitate the development of a national immunization tracking system." "The purpose of this initiative is to eliminate barriers to immunization not create more of them." "I am arguing against a large public bureaucracy. I am arguing that while we need to rebuild the public health delivery system because it is very weak and heavily used by the very poor individuals, that we should not be in the process of destroying the role of private pediatricians and private family physicians and their patients."

Mr. Chairman, as a parent and a former social worker, it was obvious to me that the administration's program was doomed to fail because it was based on the politically correct denial of the real problems. The realization that parents have an important responsibility to their children was clearly missing.

Prior to my entry into politics, I was a child welfare case worker, as was my wife. We spent a lot of time in the homes of families where there was less than ideal parenting skills, where we needed to educate the parents, where we needed to coax parents and, in some cases, where we needed to require parents to do the things that were necessary for their children.

I felt that there was a great deal of logic, however, to an approach which I co-authored with Scott Klug and Judd Gregg to require parents whose children were participants in federally supported programs like AFDC, day care and Head Start to get their children immunized as a requirement of program participation.

It is well documented that by the time children start school in States which require them to be immunized, 95 to 97 percent of them are. The Secretary's response to this suggestion was, "We have to see this program as a national program for every American child, and have to see the public interest in it and, therefore, the design has to be focused beyond just our poverty programs." So, together with the largest tax increase in American history, $250 billion over 5 years, Americans were the recipients of a new entitlement program, the Vaccines For Children Program at an estimated cost of $4.7 billion over 5 years.

As enacted, the law established a program under which each State was required to amend its medical plan to include a pediatric vaccine distribution program. States are entitled to receive pediatric vaccines purchased by the Federal Government for federally eligible children.

A year ago we were faced with the inevitable bureaucratic outgrowth of this poorly conceived big government approach to childhood immunization. The Center for Disease Control with no basis of support, proposed a creation of a central warehouse run by GSA to replace the well-established private distribution center.

CDC wasted over $700,000 in Federal funds before the Congress insisted that this ludicrous idea be dropped. In testimony before the Senate Finance Committee in May 1995, the General Accounting Office reported that "the findings from CDC diagnostic studies indicate that most underimmunized children have access to free vaccine through Medicaid or public health clinics and that they had

visited their providers an average of six to eight times during a given year. During these visits, these children could have received their scheduled immunizations, but providers failed to vaccinate them.

At the same time, Irwin Redlener, President of the Children's Health Fund, noted: "Under current VFC guidelines there is insufficient monitoring and oversight of under what circumstances and for how long these families would be eligible for free or subsidized vaccine. VFC should not offer opportunities for States to use limited public resources to provide free or subsidized vaccines to non-needy or insured patients." Mississippi State health officer, Dr. F.E. Thompson said it best when he noted: "Even as originally proposed, VFC would have had little, if any, impact in raising immunization levels. The cost of vaccine was not the problem in the first place, and making more vaccine available at public expense was not the solution." However, as originally proposed, the VFC was, at best, overkill and at worst wasteful spending. Spending a huge amount of money for a minimal impact on immunization levels.

Mr. BILIRAKIS. Please finish up, Mr. Greenwood.

Mr. GREENWOOD. I will.

It is up to this committee, Mr. Chairman, to determine if taxpayers and the Nation's children are getting their money's worth. I don't think they are.

I appreciate the opportunity to participate in this important hearing and look forward to a constructive dialog with our witnesses.

[The prepared statement of Hon. James C. Greenwood follows:

PREPARED STATEMENT OF HON. JAMES C. GREENWOOD, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF PENNSYLVANIA

Twenty-six months ago (April 21, 1993), the members of the Health and the Environment Subcommittee joined the members of the Senate Labor and Human Resources Committee to hear the Secretary of HHS, Donna Shalala, unveil the Administration's Comprehensive Child Immunization Proposal.

The Secretary unveiled the President's universal purchase plan that would ensure that all children, including mine, would have access to a new entitlement program guaranteeing them government-purchased vaccines free of charge.

I would like to take a moment to share with some of my colleagues, who were not on the Committee at the time, a few of Secretary Shalala's comments.

> "American families are getting squeezed by the skyrocketing prices of vaccines." (page 40)
>
> "The high price of vaccines is a significant financial barrier to obtaining vaccinations for preschool children." (page 41)
>
> "Our plan will eliminate financial barriers that impede the timely vaccination of children and facilitate the development of a national immunization tracking system." (page 41)
>
> "The purpose of this initiative is to eliminate barriers to immunization, not create more of them." (page 42)
>
> "I am arguing against a large public bureaucracy. I am arguing that while we need to rebuild the public health delivery system because it is very weak and heavily used by very poor individuals, that we should not in the process destroy the role of private pediatricians and private family physicians and their patients." (page 53)

The realization that parents have an important responsibility to their children was clearly missing. Prior to my entry into politics, I was a child welfare case worker—as was my wife. We spent a lot of time in the homes of families where there were less than ideal parenting skills, where we needed to educate the parents, where we needed to coax parents, and in some cases, where we needed to require parents to do the things that were necessary for their children.

As a parent and a former child welfare social worker, it was obvious to me that the Administration's program was doomed to fail because it was based on the politically correct denial of the real problem.

I felt that there was a great deal of logic to an approach, which I coauthored with Scott Klug and Judd Gregg, to require parents, whose children were participants in federally supported programs like AFDC, WIC, daycare and Head Start, to get their children immunized as a requirement of program participation. It is well documented that by the time children start school in states that require them to be immunized, 95%-97% are.

The Secretary's response to this idea was, "we have to see this program as a national program for every American child and have to see the public interest in it, and therefore the design has to be focused beyond just our poverty programs."

And so, together with the largest tax *increase* in American history—$250 billion over 5 years—Americans were the recipients of a new entitlement program—the Vaccines for Children Program—at an estimated cost of $4.7 billion over 5 years.

As enacted, the law established a program under which each State was required to amend its Medicaid plan to include a pediatric vaccine distribution program. States are entitled to receive pediatric vaccines purchased by the Federal government for federally eligible children.

A year ago (June 1994) we were faced with the inevitable bureaucratic outgrowth of this poorly conceived, big government approach to childhood immunization. The Center for Disease Control (CDC), with no basis of support, proposed the creation of a central warehouse, run by GSA, to replace the well-established private distribution center. CDC wasted over $700,000 in federal funds before the Congress insisted that this ludicrous idea be dropped.

In testimony before the Senate Finance Committee in May 1995, the General Accounting Office reported that "the findings from CDC diagnostic studies indicate that most under-immunized children have access to free vaccine through Medicaid or public health clinics and that they had visited their providers an average of six to eight times during a given year. During these visits, these children could have received their scheduled immunizations, but providers failed to vaccinate them.

At that same hearing, Irwin Redlener, President of the Children's Health Fund, noted, "Under current VFC guidelines, there is insufficient monitoring and oversight of under what circumstances and for how long these families would be eligible for free or subsidized vaccine...VFC should not offer opportunities for states to use limited public resources to provide free or subsidized vaccines to non-needy or insured patients."

Mississippi's State Health Officer, Dr. F. E. Thompson, said it best when he noted, "Even as originally proposed, VFC would have had little if any impact in raising immunization levels. The cost of vaccine was not the problem in the first place, and making more vaccine available at public expense was not the solution. However, as originally proposed, the VFC was at best overkill, and at worst wasteful, spending a huge amount of money for a minimal impact on immunization levels. As it now exists, at least in some states, the VFC itself stands to become a major barrier to improving immunization levels, and is very likely to lower them."

The important policy questions which were raised in April 1993 remain relevant today:

- What is the most effective way to make sure that all kids are vaccinated and to ensure healthy kids?
- Is it cost-effective for individuals who can afford to purchase vaccines for their children to be given free vaccines or does it add unnecessarily to the cost of the program? Are our limited resources being targeted wisely?
- What responsibility do parents have in ensuring that their children receive proper vaccinations? What is the role of health care providers?
- What has experience shown? Have the intended beneficiaries been reached?
- Has the program affected vaccine development and innovation?

It is productive to debate strategies about how to best protect and immunize our children. But the Congressional Budget Office estimates that this program will cost taxpayers $2.1 billion over the next five years. The cruelest thing we can do to this Nation's children, at a time when federal spending is mortgaging their future, is to dedicate $2.1 billion to a program which everyone agrees is not working, and which has not showed any results.

I continue to believe that the most effective way to insure that children receive the immunizations recommended by pediatricians is to require their parents to have their children vaccinated as a precondition to receive government subsidized day care, AFDC, WIC, food stamps, preschool and school services. The record is clear on this. But the Administration has insisted on pursuing its command and control, Big Brother approach to immunizing children.

It is up to this Committee to determine if taxpayers, and the Nation's children, are getting their money's worth. I don't think they are.

I appreciate the opportunity to participate in this important hearing, and look forward to a constructive dialogue.

Thank you.

Mr. BILIRAKIS. I thank the gentleman for his great statement.

Dr. Ganske.

Mr. GANSKE. Mr. Chairman, I thank you for calling this hearing. I am pleased to join you today as we continue our examination of Medicaid.

Today's hearing will highlight the fundamental cause of rapid increases in health care spending and that is expanding entitlements. I agree with my colleagues, Dr. Coburn and Mr. Towns, that the fundamental reason that children under school age are not vaccinated is lack of parental education, parental responsibility, and outreach.

Why are children 5 years and older vaccinated almost 100 percent? It is because they can't go to school if they aren't. I think we need to look at a basic premise of the program, that the solution to the problem is basically cost. I believe that we should look instead at some of the solutions to this problem that some of the States have applied.

In 1992 Maryland began reducing a family's welfare grants by $25 a month for every preschooler who wasn't properly immunized. The State also gives $20 bonuses for every family member that receives an annual checkup. It is this type of carrot and stick approach that I think would be more effective.

Thank you, Mr. Chairman.

Mr. BILIRAKIS. The gentleman's time has expired.

Mr. Burr.

Mr. BURR. Mr. Chairman, in the sake of time, I am going to forego an opening statement, but I would like to thank the Chair for this hearing so that we can get a program that does immunize children.

Mr. BILIRAKIS. I thank the gentleman.

Without objection, any member of the committee's written statement will be made a part of the record.

Mr. Whitfield.

Mr. WHITFIELD. Mr. Chairman, I also want to thank you for holding these hearings. I would also like to express my concern about the program and I look forward to the balance of the hearing.

Mr. BILIRAKIS. I thank the gentleman.

Mr. Stearns.

Mr. STEARNS. Mr. Chairman, I too would like to offer this opening statement, and I think it is important.

Particularly many of us who protested against the Clinton's health care bill to put into the record some of these comments because what has happened here with this Vaccines For Children Program has been a sad story, and I think we need to talk about the elements of this both as a tragedy and a farce.

A tragedy because their could have been a bipartisan effort to address the real issue which is lack of parental responsibility for full vaccination. By carefully targeting funds and providing incentives for poor families, Congress could have attempted to solve the real

problem. Instead the administration went on this huge wild goose chase identifying the vaccine price as a major barrier.

The program is a farce because from its inception the VFC Program has been driven by the administration's one-dimensional request to nationalize the vaccine supplies. This quest leads to unreasonable interpretations of the underlying statute, bureaucratic bumbling, and ended in a train wreck, as I will mention later, in a warehouse in New Jersey.

But let's start just briefly with Act One, from the beginning. The administration began in January 1993 its campaign for universal health care reform by making the decision that it could succeed in the health care reform debate by threatening and intimidating the pharmaceutical companies. Many remember that. This administration appeared to believe that the health care reform should be conducted by a war.

So in 1993, the pharmaceutical industry was identified as Public Enemy Number 1, do you remember that? The administration stated that the health care system was being ripped off, and made perhaps an outrageous propaganda statement of saying they were profiting at the expense of our children. I think we should remember that statement.

As Senator Bumpers and other members of the President's own party pointed out, this information about the explanation had to do more with the failure of many parents to take advantage of free immunization programs and government's own failed efforts to immunize the poor. But truth took a backseat to this message, and it is clear to many of us that the administration's original proposal to provide vaccines free to all children as it was proposed was basically a new entitlement, an effort to perhaps nationalize the entire vaccine industry.

As the VFC Program moved through the legislative process, it was trimmed back considerably, but it still contained a number of problems. First, it shifted the market for vaccines dramatically to the public sector. Under this program, CDC estimated that the government would purchase almost 80 percent of all vaccines. Not only does the government pay a heavily discounted price, but the program placed a price control on future price updates. Clearly this created a "chilling" effect on future vaccine research and development.

Act Two, where the administration attempted to implement the legislation, we entered the theater of the absurd. The episodes began with a drafting error in the legislation, an occurrence not uncommon here in Washington. The problem centered around sections dealing with the cost of the delivery of vaccines.

The administration specifically read the statute to require that the cost of delivery of vaccines to providers be included within the cap price. This was a fatal flaw in the program because everyone agreed that it was economically impossible to deliver the vaccine to physician's offices for this price.

In a letter dated November 8, 1993, to Secretary Shalala, Chairman Dingell, Waxman and Moynihan basically tell the Secretary they would consider offering a technical correction to the legislation that would delete the requirement. Unbelievably, the Secretary in her reply rejects the request to correct the statutory language as-

suring the chairman that the program "will be fully and effectively implemented." Now our story moves to a paint plant warehouse in New Jersey. CDC had a brainstorm, the kind only a large government bureaucracy would have: why not store and distribute a large portion of our Nation's vaccine supply from an old paint warehouse in New Jersey? How CDC thought that an old paint warehouse could meet FDA's elaborate standards for storing and delivering vaccines is a question that hopefully Dr. Satcher, the Director of CDC, can answer today.

Here is what GAO said about this idea. "The Federal Government has no experience with storing, packaging and delivering vaccines. The Agency's warehouse in New Jersey currently handles approximately 5,000 commodities, including office products, paper, hardware, tools, paint, solvent, and adhesives." Beyond the issue of the facility, CDC proposed that they could deliver about 70,000 sites like this around the United States. Well, that died because at the first blush it cost $700,000 before they went further.

Now, Mr. Chairman, we move to Act Three.

Mr. BILIRAKIS. The gentleman's time has expired, please finish up.

Mr. STEARNS. Okay. I will summarize by saying Act Three, again, shows that Congress' attempt to implement this program became a farce.

Let me conclude by saying this, this program cannot be fixed. We in this committee can fix it through the Medicaid block grants, and I think now is the time to do it.

Thank you, Mr. Chairman.

Mr. BILIRAKIS. I thank the gentleman and I apologize for cutting him off, he was on a roll there.

[The prepared statements of Hon. Cliff Stearns, Hon. Sherrod Brown, and Hon. Fred Upton follow:]

PREPARED STATEMENT OF HON. CLIFF STEARNS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF FLORIDA

Mr. Chairman, the administration's handling of the Vaccine For Childrens' Program has been a sad story from its inception approximately two years ago. It's a story that has elements of both tragedy and farce.

Tragedy, because there could have been a bi-partisan effort to address the real issue in under-vaccination, which is the lack of parental responsibility for full vaccination. By carefully targeting funds and providing incentives for poor families, Congress could have attempted to solve the real problems. Instead the administration went on a "wild goose chase" identifying vaccine price as the major barrier.

Farce, because from its inception, the VFC Program has been driven by the administration's one dimensional quest to nationalize the vaccine supply. This quest lead to unreasonable interpretations of the underlying statute, bureaucratic bumbling, and ended in a "train wreck" in a warehouse in New Jersey.

But let's start from the beginning, at Act 1. Long ago—it was really only January 1993—the administration began its campaign for universal health care reform by making the decision that it could succeed in the health care reform debate by threatening and intimidating the national pharmaceutical companies, health insurers and providers. This administration appeared to believe that health care reform should be conducted as a war, rather than as a debate. Of course, in every war you need enemies.

So in 1993, the pharmaceutical industry was identified as "public enemy number 1." The administration stated that the health care system was being "ripped off" by "price gouging" drug companies. In the most outrageous and false propaganda statements, they said that companies were attempting to "profit at the expense of our children." Well, as Senator Bumpers and other members of the President's own party pointed out, the explanation had to do more with the failure of many parents

to take advantage of free immunization programs and government's own failed efforts to immunize the poor. But truth took a "back seat" to propaganda, and the war had begun.

It is clear to many of us that the administration's original proposal, which was to provide vaccines free to all children as an entitlement, was really an effort to nationalize the entire vaccine industry. This proposal was the "opening salvo" for the Clinton health care bill which placed a wide array of price controls, rebates, and outright black-listing on the pharmaceutical industry.

As the VCF Program moved through the legislative process it was trimmed back considerably, but it still contained a number of problems. First, it shifted the market for vaccines dramatically to the public sector. Under this program, CDC estimated that the government would purchase almost 80 percent of all vaccines. Not only does the government pay a heavily discounted price, but this program placed a price control on future price updates. Clearly, this created a "chilling effect" on future vaccine research and development.

In Act 2, where the administration attempts to implement the legislation, we enter the *"theater of the absurd."* This episode begins with a drafting error in the legislation, a not uncommon occurrence in reconciliation bills of thousands of pages. The problem centered around sections dealing with the cost of the delivery of vaccines. The administration specifically read the statute to require that the cost of delivery of vaccines to providers be included within the capped price. This was a fatal flaw in the program, because everyone agreed that it was economically impossible to deliver the vaccine to physician offices for this price.

In a letter dated November 8, 1993, to Secretary Shalala, Chairman Dingell, Waxman, and Moynihan basically tell the Secretary that they would consider offering a technical correction to the legislation that would delete the requirement.

Unbelievably, the Secretary in her reply rejects the request to correct the statutory language assuring the chairmen that the program "will be fully and effectively implemented."

Now our story moves to a paint warehouse in New Jersey!! CDC had a "brain storm"—the kind only a large government bureaucracy could have. Why not store and distribute a large portion of our Nation's vaccine supply from an old paint warehouse in New Jersey. How CDC thought that an old paint warehouse could meet FDA's elaborate standards for storing and delivery vaccines is a question that hopefully Dr. Satcher, the Director of CDC, can answer today. Here is what GAO said about the warehouse:

> The Federal Government "has no experience with storing, packaging, and delivery vaccines." The Agency's warehouse in New Jersey "currently handles approximately 5,000 commodities, including office products, paper, hardware, tools, paint, solvents and adhesives."

Beyond the issue of the facility, CDC proposed that they could deliver to over 70,000 sites using Federal Express overnight delivery. Well, after wasting $700,000, Congress killed this preposterous proposal.

Now we move to Act 3. With the warehouse delivery system dropped, the administration had gone full circle and were again stuck with their restrictive reading of the statute. On August 25, 1994 Chairman Dingell, Waxman, and Donald Riegle wrote again to Secretary Shalala that *Congress did not intend to restrict vaccine payments for direct delivery to the capped price.* On September 21, 1994, the General Council's office of HHS totally reversed their earlier position, and agreed that for direct delivery, the Federal payment would be in addition to the capped price. Consequently, almost an entire year was wasted in reaching this obvious conclusion.

Today, GAO has given us its current evaluation of the program. They have reviewed the program in terms of 7 major implementation tasks and have found that 6 of the 7 remain incomplete or problematic.

This is a program that cannot be fixed. It is a fitting metaphor of the administration's entire approach to health care reform. As we move into reconciliation to balance the budget, I am confident that this program will end inside our approach to Medicaid block grants.

PREPARED STATEMENT OF HON. SHERROD BROWN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF OHIO

Mr. Chairman, at a time when more and more families are losing their health insurance coverage, the Vaccines for Children Program is essential to ensure access and coverage for critical immunizations in a timely manner.

It is absurd to argue that the cost of vaccines is not a barrier to access. In certain areas of Northeast Ohio, rates are as low as 46 percent—less than half of the chil-

dren in certain communities receive age appropriate, timely immunization for debilitating—and sometimes deadly—illnesses.

It is one thing to cut the budget for the sake of cutting the budget, but this doesn't make sense. Immunization is cost-effective. Vaccination can save anywhere from $10 for every dollar invested up to $35-$50 for every dollar invested. Yet, the majority has targeted this program for elimination as a budget-cutting measure. It doesn't make sense to cut those investments that save public dollars in the long run.

The GAO has analyzed this program and criticized its implementation when it has been in effect for less than six months. Yet in Elyria, Ohio, the Health Commissioner is delighted to see that more kids are being immunized on time, more providers are available to offer free immunization, there are improved clinic hours and better outreach and education.

In sum, I believe the VFC shows many successes in Ohio despite the short time it has been implemented. Mr. Chairman, I hope we will highlight these successes today.

PREPARED STATEMENT OF HON. FRED UPTON, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MICHIGAN

Thank you, Mr. Chairman.

Our hearing today will focus on the Vaccines for Children Program, which came into existence in the Omnibus Budget Reconciliation Act of 1993 (OBRA '93) over unanimous Republican opposition. While the goals of this program are certainly noteworthy; namely, to assure that every child in the US receives their vaccinations, I am concerned that the reality of the program has not lived up to the theory.

My home state of Michigan has had a very interesting relationship with the Vaccines for Children Program. As some may know, Michigan is one of two states which manufactures its own DTP vaccine. As such, Michigan is entitled to a cash payment from the federal government in lieu of using the vaccines available through VFC. Last year, the federal government sent $11 million to Michigan to make up for the DTP that Michigan already produces.

This is very important, in that Michigan is forced to pay a vaccine excise tax to the federal government. Even though the state distributes the vaccine free of charge, they must pay into the vaccine compensation fund. This fund is used to compensate those few children who have an adverse reaction to vaccines. This excise tax is paid for by the $11 million dollars

Because the VFC program has been reasonably effective in Michigan, I was disappointed to read the General Accounting Office report on the program. When I see the benefits the program brings back to my state, the report is certainly sobering.

The experiences in the state of Michigan do not mean that this program is perfect, or that revising the program is out of the question. Suggestions have been made to alter the program so that it is not necessarily an entitlement; but that it would make sure that it covers those children in poverty. In the final analysis, the federal government must assure that children can get vaccines; the GAO report suggests that we must do more than just be concerned about the cost.

I look forward to hearing from our witnesses today, and I yield back the balance of my time.

Mr. BILIRAKIS. Our first witness this morning is Mr. Kwai-Cheung Chan of the General Accounting Office. Mr. Chan, please come forward.

He is accompanied by Dr. Sushil Sharma, and William Hadesty. The GAO has been following the implementation of the VFC Program since it inception, and today they will provide the results of their ongoing work at the request of Senator Bumpers and Congressmen Klug and Wyden.

Mr. Chan, I would ask you to keep your oral testimony to 10 minutes. Of course, your written testimony is made a permanent part of the record, sir.

Thank you.

Please proceed.

STATEMENT OF KWAI-CHEUNG CHAN, DIRECTOR, DIVISION OF PROGRAM EVALUATION AND METHODOLOGY, GENERAL ACCOUNTING OFFICE, ACCOMPANIED BY SUSHIL SHARMA

Mr. CHAN. Thank you, Mr. Chairman, and members of the subcommittee.

Thank you for introducing my colleagues, and it is a pleasure to be here today. I can't see anything without my glasses, I am sorry. Getting old.

It is a pleasure to be here today to share the results of our work on the Vaccines For Children or VFC Program which is explained in detail in a report that we are issuing today.

In my testimony, I will present our conclusion on, (1), the extent to which vaccine cost has prevented children from being immunized on schedule; (2), the VFC implementation; and, (3), the promising options for improving children's immunization rates.

As you indicated in your opening statement, Mr. Chairman, the VFC Program, which began on October 1, 1994, provides free vaccines for children who are Medicaid eligible, American Indians, uninsured, and whose insurance does not cover the cost of vaccines.

The goal of this program is to increase immunization rates, particularly among preschool children by providing free vaccines and, thereby, reducing vaccine costs as a barrier to immunization.

As an entitlement program, VFC has no fixed budget. Its fiscal year 1995 cost estimate includes $412 million for vaccine purchase and about $45 million for administrative expenses.

This budget is expected to go up as new vaccines are incorporated in the schedule by ACDP. For example, CDC officials estimate that initial VFC purchases of new chicken pox vaccine would cause an additional $35 to $560 million.

Today, I have four findings to report. These findings underpin our view that the VFC goal needs to be reassessed.

First, vaccine cost, as it has been stated a lot already by the opening statements of the members, we conclude that the cost of vaccines has not been a major barrier to children's timely immunization.

We found, that at the outset of VFC the immunization rates for preschool children as of May 1994, exceeded the 90 percent national goal for 1996 for two antigens.

Further, regardless of vaccine costs, immunization rates amongst school children already exceeds 95 percent for all antigens in the basic series.

In addition, we found that other barriers are more important than vaccine costs.

Studies identify many barriers, including inadequate clinic resources, clinic policies that deter vaccination and various other factors that cause providers to miss opportunities to immunize children at regular visits.

Finally, most children who had not received vaccination had access to free vaccines through Medicaid or public health clinics even before VFC.

The second one, on pockets of need. The problem of under-immunization is concentrated in certain groups and areas often referred to as pockets of need by researchers. In these areas, there

are disproportionate numbers of children who are not immunized for specific diseases, creating conditions ripe for disease outbreak.

The goal of the VFC is to achieve a national immunization goal of 90 percent by 1996, but when you look at distributions of rates by localities you will find that even if one achieved that goal, there will still be areas where underimmunization would be quite high.

We find that, for example, as the charts show that only 17 of the over 3,000 counties in the United States consistently reported measle cases over a 10-year period, and there are many other statistics one can show, but that is just an example. This suggests that targeting immunization efforts to pockets of needs might be more cost effective in improving immunization rates.

The third finding is on program implementation, and within that I have a number of subtopics to talk about. As you noted, Mr. Chairman, we reported in July 1994 that the original CDC plan to implement VFC by October 1, 1994, was very ambitious given its scope and the inherent complexity and interdependency of tasks. We question its ability to accomplish those tasks adequately by the State. However, HHS asserted that these problems could be rectified and announced that this program would be fully implemented by October 1, 1994.

Although CDC has devoted considerable efforts and resources to implementing VFC and has made progress, in our review, we found that 6 of the 7 VFC critical implementation tasks remain incomplete. The only completed task is contract negotiation for the purchase of vaccines.

Let me go to those six tasks. Vaccine distribution, CDC had problems distributing VFC vaccines to private providers. In early 1994, CDC officials indicated that since the law did not permit the Agency to reimburse manufacturers separately for delivery of vaccine purchased under the price caps, it would distribute the vaccine through a national distribution center under GSA.

However, plans for the national distribution center were dropped in August 1994. In an apparent contradiction, an attempt to amend its contract with four vaccine manufacturers to provide separate payment for delivery services, CDC solicited and received sole-source bids from the four vaccine manufacturers by December 1994, but withdrew its solicitation in April 1995 because, by then, many States had made alternative distribution arrangements with CDC's financial assistance.

As of March 1995, 15 of the 24 States that had expected to rely on a national distribution center had not begun routine vaccine delivery to the private providers.

In terms of provider enrollment, while the States had enrolled most public health providers as of January 1995, CDC and many States cannot gauge the proportion of private Medicaid providers that had been enrolled.

In early 1994, CDC said that it hoped for 50 percent enrollment of private providers but had no specific State goals.

In January 1995, 46 States had begun their enrollment, but in our survey of the States, only 30 of these could provide estimates of proportions of providers that had been enrolled. Of these 30, 13 reported a 50 percent enrollment or more, and 9 reported 10 percent or less.

The Health Care Financing Administration plans to terminate Medicaid vaccine payment in October 1995 when VFC vaccines are available to private providers, supposedly. Thus, monitoring the proportion of Medicaid physicians who have enrolled in VFC is the only way of ensuring that Medicaid beneficiaries access to immunization will not be disrupted.

In terms of provider reimbursement, under the law provider's fee for administrating VFC vaccine is to be based on their actual cost for providing the service. Although CDC had set caps on administrative fees, it based these caps on the physician's prevailing charges instead of costs.

In February 1995, HCFA officials told us that they have engaged the Center for Health Policy studies to collect data for designing cost-based maximum fee schedules. As of May 12, the research protocol was still under review in OMB.

In terms of order processing and automation, CDC developed and provided States with software and hardware known as VACMAN to assist them in ordering, tracking and recording the cost of publicly funded VFC vaccines by processing both public and individual private provider vaccine orders, recording data on all enrolled public and private providers, accounting for orders by funding sources, and electronically linking CDC and the 64 State immunization projects.

During fiscal year 1994, CDC developed and distributed the system at a cost of just under $1 million.

One, we found that CDC did not allow enough time to test VACMAN operationally before October 1, 1994, which is the start date.

Two, did not actively involved the systems users to ensure that their functional needs would be met.

Three, did not perform alternative system designs and cost/benefit analysis to determine that its the best system to support VFC's objective.

It is not designed to meet the critical needs of VFC.

Mr. BILIRAKIS. Dr. Chan——

Mr. CHAN. Yes.

Mr. BILIRAKIS. I would imagine during the questioning probably many of your other points can be brought up, but I would like to ask if possibly either of the gentlemen accompanying you might very briefly like to supplement your statement.

They are welcome to if they'd like to.

Mr. CHAN. Okay.

[The prepared statement of Kwai-Cheung Chan follows:]

PREPARED STATEMENT OF KWAI-CHEUNG CHAN, DIRECTOR, DIVISION OF PROGRAM, EVALUATION AND ACCOUNTING, GAO

Mr. Chairman and Members of the Subcommittee: It is a pleasure to be here to share with you the results of our work on the Vaccines For Children (VFC) program. My statement is based upon our work in this area for the report that we are issuing today.[1] As you requested, today we will present our conclusions on (1) the extent to which vaccine cost has prevented children from being immunized on schedule, (2)

[1] U.S. General Accounting Office, *Vaccines For Children: Reexamination of Program Goals and Implementation Needed to Ensure Vaccination*, GAO/PEMD-95-22 (Washington, D.C.: June 1995).

VFC's implementation, and (3) promising options for improving children's immunization rates.

Before turning to the results of our work, let me briefly provide some basic information on VFC. Section 13631 of the Omnibus Budget Reconciliation Act of 1993 created VFC to begin by October 1, 1994, as an entitlement program for four groups of children through 18 years old: those eligible for Medicaid and those who are American Indians or uninsured. Underinsured children (those whose insurance does not cover childhood vaccinations) are also eligible for VFC vaccines but may receive them only in federally qualified health centers or rural health clinics. CDC views VFC's goal as increasing immunization rates, particularly among preschool children, by providing free pediatric vaccines and, thereby, reducing vaccine cost as a barrier.[2]

Its fiscal year 1995 cost estimates included $412 million for vaccine purchase, $24.5 million for vaccine distribution, $9.2 million for vaccine ordering, and $11.6 million for operations. The Centers for Disease Control and Prevention (CDC) has announced that doses of influenza vaccine for high-risk children and hepatitis B for adolescents will be added to the recommended schedule in fiscal year 1996, along with speedier catch-up immunization against measles. Newly approved varicella (chicken pox) and hepatitis vaccines will be considered. Only one of these five new additions to the vaccine schedule (the measles booster) will be covered by statutory price caps (that is, contract prices that were in effect in 1993). CDC officials estimate that VFC purchases of the new varicella vaccine could cost an additional $35 million to $560 million, depending on the extent of catch-up coverage recommended. CDC estimates that once catch-up has been completed, the annual cost of including varicella will range from $35 million to $70 million.

METHODOLOGY

To perform our review, we examined pertinent literature, data, and agency documents, met with CDC officials, and convened a panel of the principal investigators on four major CDC-funded studies that "diagnosed" and identified reasons for low immunization rates among inner-city preschoolers in Baltimore, Los Angeles, Philadelphia, and Rochester, New York. We also surveyed all 50 states and the District of Columbia and interviewed other federal and state officials, vaccine experts, representatives of vaccine manufacturers and distributors, and physicians.

STUDY RESULTS

Turning to our results, I would like to cover four areas that underpin our view that VFC's goal needs to be reassessed. These areas are vaccine cost, pockets of underimmunization, VFC's implementation, and promising options for improving children's immunization rates.

Vaccine Cost

From the available evidence, we conclude that the cost of vaccine for parents has not been a major barrier to children's timely immunization. Immunization rates for preschool children at the outset of VFC were at or near the 90-percent national goal for 1996. Further, immunization rates among school children now exceed 95 percent for all antigens in the basic series. Four major CDC studies suggest that other barriers are more important than vaccine cost. These and other studies identify many barriers, including inadequate clinic resources, clinic policies that deter vaccination, and various factors that cause providers to miss opportunities to immunize children at regular visits. In fact, when VFC began, most children who had not received age-appropriate vaccinations had already had access to free vaccine through Medicaid or public health clinics, but their health care providers had missed opportunities to vaccinate them during routine visits.

The evidence that CDC has relied on to suggest that vaccine cost is a major barrier tends toward more narrow investigations of particular factors, such as providers' referral patterns. We found that, for the purpose of assessing the role of vaccine cost in underimmunization, this research suffers from several conceptual and methodological problems. One is the failure to separate vaccine costs, which VFC addresses, from the larger provider fees associated with immunization, which it generally does not. The statute does stipulate that providers may not deny vaccine to a child who is unable to pay the administration fee. However, CDC has no measures to ensure the providers' compliance with this requirement. Another problem with the research is its inability to determine that the factors actually measured, such

[2] The vaccines VFC provides to the states include antigens for measles, mumps, rubella, diphtheria, tetanus, pertussis, polio, hepatitis B, and haemophilus influenza.

as provider referrals to public health clinics, are valid indicators of whether children are or are not immunized. And, too, much of the research relies on opinion data collected in surveys rather than through an analysis of the immunization status of representative samples of children.

Pockets of Need

It is important to note that the problem of underimmunization is largely concentrated in certain population groups and areas often referred to as "pockets of need." In these groups and areas, there are disproportionate numbers of children who are not immunized for specific diseases, creating conditions ripe for disease outbreak. For example, CDC's analysis of the measles outbreaks in the 1980s shows that delayed immunization led to consistently reported cases over 10 years in only 17 of 3,137 U.S. counties, suggesting that special efforts to improve immunization coverage might be targeted there.

Program Implementation

Although CDC has devoted much effort and considerable resources to implementing VFC, and has made progress, VFC's implementation remains incomplete. We reported in July 1994 that the original CDC plan to implement VFC by October 1, 1994, was very ambitious given its scope, the inherent complexity and interdependence of tasks, and the need for strong leadership to coordinate the efforts of various federal, state, and private sector partners.[3] We questioned CDC's ability to accomplish those tasks adequately before October 1994. However, the Department of Health and Human Services (HHS) asserted that these problems could be rectified and announced that VFC would be *fully* implemented by October 1, 1994.

For today's report, we reviewed the status of contract negotiation, provider enrollment, provider reimbursement, order processing and automation, vaccine distribution, accountability, and evaluation planning as of March 30, 1995. We found that six of these seven critical implementation tasks remain incomplete.

Vaccine Contracts

The only completed task is contracting to purchase vaccines. Even here, two problems have emerged. First, some states have objected that CDC's order processing methods do not permit them to guarantee physicians specific brands of vaccine.[4] Many physicians believe that different brands of vaccine are not interchangeable.

Second, CDC officials told us that the maximum doses of oral polio vaccine (OPV) that can be purchased under the current contract will not meet the estimated needs of all the states for fiscal year 1995. This problem may only get worse, since 14 states and the District of Columbia have yet to begin routine ordering for private providers.[5] This would result in a shortage of the polio vaccine for VFC unless CDC draws it from the stockpile, which CDC officials describe as a last resort, or buys additional vaccine outside the existing contract. Buying OPV outside the contract at prices that exceeded the statutory caps would create questions about CDC's ability to comply with the law.[6]

Vaccine Distribution

CDC has had problems distributing VFC vaccines to private providers. CDC's policy has shifted considerably in this regard. At first, CDC officials indicated that since the law did not permit the agency to reimburse manufacturers separately for *delivery* of vaccine purchased under the price caps, it would distribute vaccine through a national distribution center under the General Services Administration. However, plans for a national distribution center were dropped in August 1994, and CDC, in apparent *contradiction,* attempted to amend its contracts with four vaccine manufacturers to provide separate payments for delivery services. CDC solicited and received sole-source bids from four vaccine manufacturers by December 1994 but withdrew its solicitation in April 1995 because many states had made alternative distribution arrangements with CDC's financial assistance. As of March 30, 1995, 15 of the 24 jurisdictions (23 states and the District of Columbia) that had expected to rely on a national distribution center had not begun routine vaccine delivery to

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[3] U.S. General Accounting Office, *Vaccines For Children: Critical Issues in Design and Implementation,* GAO/PEMD-94-28 (Washington, D.C.: July 1994).

[4] Under current contracting arrangements, such a guarantee might not be possible 100 percent of the time, but systems might be improved to optimize the satisfaction of providers' preferences.

[5] These 15 jurisdictions represent more than 1.3 million children, or more than 45 percent of the children younger than 2 who the states estimated would receive VFC vaccine from private providers.

[6] If the OPV contract does not permit the purchase of sufficient quantities of vaccine to meet VFC's needs, it will be important for CDC to give VFC's acquisitions priority over those made at state option.

private providers. As a result, private providers in 14 states and the District of Columbia will not be able to immunize entitled children with free VFC vaccines.

While the states that have decided to develop their own distribution systems will be fully reimbursed for distribution costs through VFC, these costs are not capped, and the states do not have to contribute to them. Other than reviewing state funding requests, CDC has provided no guidance to the states on how to deal with distribution costs, which have differed considerably depending on state solicitation and contracting procedures.

Provider Enrollment

While the states had enrolled most public health providers as of January 30, 1995, CDC and many states cannot gauge the proportion of private or Medicaid providers that have been enrolled. CDC does not know the numbers of eligible pediatricians, family practitioners, osteopaths, Medicaid providers, and other private providers and therefore cannot accurately assess the proportions of immunizing providers who have been enrolled.

In early 1994, CDC said that it hoped for 50-percent enrollment of private providers but had no state-specific goals. In January 1995, 46 states had begun their enrollment but only 30 of these could provide estimates of the proportion of providers who had been enrolled. Of these 30, only 13 reported 50-percent enrollment or more.[7] Of the remaining 17 states, 8 reported 11 to 49 percent enrollment and 9 reported 10 percent or less. These 17 states represent about one third of the children likely to receive VFC vaccines through the private sector.

About 60 percent of the children who are eligible for VFC are also eligible for Medicaid and receive their other health care through providers enrolled in that program. The Health Care Financing Administration (HCFA) plans to terminate Medicaid vaccine payments in October 1995 where VFC vaccines are available to private providers. Thus, monitoring the proportions of Medicaid physicians who have enrolled in VFC is the only way of ensuring that Medicaid beneficiaries' access to immunization will not be disrupted. However, it is not clear whether HCFA can assess Medicaid beneficiaries' access to VFC-enrolled providers in order to determine when it is prudent to end these payments.

Provider Reimbursement

Under the law, providers' fees for administering VFC vaccine are to be based on their actual costs for providing this service. Although CDC has set caps on administration fees, it has based these caps on physicians' prevailing *charges* instead of costs. Consequently, in several states, permissible fees under VFC have exceeded Medicaid vaccine administration fees by as much as $10. CDC's rationale for using prevailing charges was that data on the cost of administering vaccine were insufficient when it developed VFC's reimbursement policy and that physicians would not otherwise enroll. As we noted in July 1994, this policy can create a financial burden for parents, who may have to pay more than under a fee schedule based on administration costs, as stipulated in the law.[8]

Order Processing and Automation

CDC developed and provided the states with software and hardware, known as VACMAN, to assist them in ordering, tracking, and recording the costs of publicly funded VFC vaccines by processing bulk public and individual private-provider vaccine orders, recording data on all enrolled public and private providers, accounting for orders by funding source (whether Section 317, state, or VFC), and electronically linking CDC and the 64 state immunization projects. During fiscal year 1994, CDC developed and distributed this system at a cost of just under $1 million.

CDC did not (1) allot enough time to test VACMAN operationally before the October 1, 1994, start date, (2) actively involve the system's users to ensure that their functional needs would be met, (3) perform alternative systems design and cost-benefit analyses to determine the best system to support VFC's objectives, or (4) perform independent quality-assurance testing of the system.

The result is that VACMAN is not designed to meet critical VFC needs, such as identifying underimmunized children or tracking those who have been vaccinated through the program. Twenty-two states said that for VACMAN to be useful, they

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[7] Of these 13, 7 were capable of expediting enrollment because they either had begun universal vaccine distribution since VFC or had implemented universal distribution programs before VFC. The 3 states reporting 90-percent enrollment or more had universal programs before VFC, but they serve less than 1 percent of the children younger than 2 who are likely to be immunized with VFC vaccines.

[8] U.S. General Accounting Office, *Vaccines for Children: Critical Issues in Design and Implementation*, p. 2.

need to link it with other systems and databases, but many states cannot. This hinders their ability to share data and fully support the VFC program.

Many of VACMAN's system functions are not being used. For instance, CDC disabled private-provider ordering functions when the national system for distributing vaccines to providers was dropped. The states can use VACMAN only for bulk ordering, thus limiting their ability to track and account for vaccines ordered by private providers. Moreover, the states perceive VACMAN's accountability as limited—only 8 states told us that VACMAN meets all their accountability needs.

Moreover, VACMAN does not provide the states with overall project fund balances, so they may not know whether they have funds to cover orders as they place them, nor does it indicate whether a vaccine is on back order, so they cannot easily determine when or whether an order will be filled. Officials in 29 states said that they operate other systems to track and manage vaccines even though this may involve dual data-entry and redundant operations. CDC plans multiple revisions to the software through the end of this year.

Accountability

Believing that strict accountability measures, such as requiring providers to report vaccine usage, might prevent them from participating, CDC mandated only that the states require providers to complete three enrollment documents.[9]

CDC's initial plan had been to use the providers' own estimates of their vaccine needs as the basis for vaccine accountability. We noted in July 1994 that this plan was inadequate and that CDC lacked any independent means of verifying state vaccine needs, and we concluded that it would not be able to detect fraud and waste. Moreover, providers' enrollment remains low, despite VFC's minimal accountability requirements.

Reversing policy in November 1994, CDC gave the states 1 month to report comprehensive accountability plans for their supplies of free vaccine. These plans contain a variety of measures; many states plan to compare providers' profiles and ordering patterns to external databases such as immunization registries. But as of March 30, 1995, no states had submitted reports to CDC, and the agency cannot distinguish between the number of children who have been immunized under VFC and the number of doses of vaccine that have been distributed, nor can it accurately assess vaccine waste.

The major federal accountability requirement is that providers estimate the number of their patients who are eligible for VFC and their vaccine needs. However, most states report that providers "greatly" or "somewhat" overestimate these numbers. CDC has found that several states relying on these estimates have projected vaccine needs that exceed the total numbers of children in the appropriate age ranges. Therefore, CDC has dropped its plans to use such data as a basis for accountability, engaging a contractor in February 1995 to study alternative measures.

In the absence of better accountability plans, CDC cannot ensure that VFC is reaching the target population, let alone underimmunized children in pockets of need, or to determine the level of waste and abuse.

Evaluation

As of May 1, 1995, CDC had released no plans for evaluating VFC, and 31 of the states we surveyed in December 1994 had no such plans. The states that did have plans generally acknowledged that they were not intended to evaluate the program's effect (versus assessing its implementation) or could not distinguish VFC's intervention from other factors that might be improving immunization rates. Forty states reported that they had initiated related programs at or near the time when VFC began. In the states that already had universal vaccine purchase programs, it is not clear that VFC will have any *direct* effect on immunization activities apart from changing the source of their financing.

CDC officials reported before VFC began that their draft VFC evaluation plans focused on the program's implementation, which CDC has begun to examine through periodic surveys of state immunization personnel.

In summary, we found ongoing problems in six of the seven areas of program implementation we examined. Although contract negotiation and enrollment of public health providers are largely complete, the enrollment of private providers appears to be low. While HCFA conducts a cost study, VFC policies governing providers' fees remain inconsistent with the law. At least 15 jurisdictions had not begun routine shipments of vaccine to private providers by March 1995. Moreover, VFC's auto-

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[9] Centers for Disease Control and Prevention, *Vaccines For Children Operations Guide* (Atlanta: May 1994), p. 22. The three enrollment documents are the provider's profile, the provider's enrollment form, and the patient's eligibility form.

mated order processing system was not developed in conformance with federal guidelines and, consequently, supports limited program functions and fails to meet important user requirements. CDC's accountability plans do not permit it to distinguish the number of children immunized with VFC vaccine from the number of doses of vaccine distributed and thus limit its capacity to monitor vaccine waste and diversion. Finally, evaluation plans were not ready as late as May 1995.

Collectively, these facts raise concerns about VFC's management and its coordination with other immunization programs. VFC's management, split across HCFA, CDC, and the states, offers little assurance of a smooth transition between VFC and other immunization programs. For example, while VFC operates in conjunction with Medicaid's immunization efforts, the two programs have not been adequately coordinated. HCFA has therefore been unable to set criteria for cut-off dates for vaccine reimbursement under Medicaid, and the data on Medicaid providers that are critical for developing VFC's provider-enrollment goals are not available.

Promising Options

CDC-funded studies have shown promise for improving immunization rates by coordinating immunization services with large public programs—such as the Special Supplemental Food Program for Women, Infants, and Children and Aid to Families with Dependent Children, which cover children who are known to be at high risk of delayed immunization and vaccine-preventable disease. Research also links improved immunization with provider-based strategies, such as assessing clinic immunization practices and offering feedback or creating reminder and recall systems or registries to reduce missed opportunities for immunization. One CDC official has testified, based on major CDC-funded research, that immunization rates for most antigens could be improved by as much as 15 percent simply by eliminating missed opportunities.

CONCLUSIONS

We conclude from the available evidence that vaccine cost has not been the major barrier for the parents of underimmunized children. Major studies indicate that free vaccine was generally available to them before VFC. Even a fully functional VFC is not likely to prevent outbreaks of vaccine-preventable disease. These outbreaks are likely to occur in pockets of need located mostly in urban areas across the nation. Data on underimmunized children in major metropolitan areas indicate that supplementary action independent of making vaccine free will be required and that efforts other than VFC may hold greater promise.

The Congress may want to consider refocusing VFC's goal from the improvement of general immunization rates to the achievement of higher immunization rates in pockets of need, where conditions are ripe for disease outbreaks among underimmunized children. A program with immunization targeted to pockets of need should be more cost-effective than the current approach. In conjunction, enrollment, accountability, automation, and evaluation efforts need to be adjusted to focus on children who are at the greatest risk for delayed immunization. Reminder and recall or tracking systems might help identify and reach them.

Mr. Chairman, this concludes my remarks. I would be happy to answer any questions that you or members of the Subcommittee may have.

Mr. BILIRAKIS. Well, I'll shift this back to the 5 minute mark.

Dr. Chan, there are a lot of specific questions which I trust probably will be raised by many of the members. This is not only a very busy committee, it used to be and probably still is the busiest committee the House but it is well attended and I am very pleased with the attendance here today.

Let me ask you a basic question. In your opinion, we all acknowledge first that vaccinating children is a very, very important aspect. It's something that we all hope will continue and continue every bit as good, if not on an improved basis over what has taken place up to now. In your opinion, if Medicaid goes on the block grant system, and I am not sure whether you are familiar with the details there and we are not that familiar with the details as yet—but in any case we're talking about giving the responsibility to the States, the dollars going to the States and then the States will decide how to use it.

Do you in your mind and in your heart feel that the States can do as good a job and potentially even a better job in terms of vaccinating our children?

Mr. CHAN. Well, let me say that we have talked to a lot of State officials and we recognize that there's a lot of other activities that are going on within States beyond VFC and there's a lot of outreach programs going on and advertisements.

We receive posters from them and, you know, they are hard at work and they understand the problem.

I think you are asking more of a finance issue, which is something that——

Mr. BILIRAKIS. No, no, I am not really talking finance as much as I am caring and concern and wanting to get something done.

Mr. CHAN. Well, let me say basically if you look at CDC, purely—the role of CDC at the Federal level alone, you find essentially HHS is really writing the checks, so there is a change in terms of who is paying for what. But as I go through the VFC so-called critical issues in terms of accountability, in terms of evaluation, in terms of listening to providers, to their role and so on, they have already been delegated to the States to do.

So what I am saying is the infrastructure side as well as the operational side, it's really been, you know, even under VFC it's been done that way.

Mr. BILIRAKIS. So in other words, in your opinion the States have actually been handling a major portion of this function, even under the VFC program.

Mr. CHAN. That's right.

Mr. BILIRAKIS. And is your answer then basically yes to my question, that you feel that they can do as good a job?

You keep looking at Mr. Waxman.

Mr. CHAN. I should be looking at him?

Mr. BILIRAKIS. No, I——

Mr. CHAN. I would agree with that in general principle, yes, sir.

Mr. BILIRAKIS. Well, you mentioned a 90–96 figure there. What is the goal of immunization in your opinion and what type of statistics are more relevant for this purpose and why?

I might ask you as an additional part of that question if you have discussed this issue with any other expert in the public health field, and if so, who is that person?

Mr. CHAN. Yes, let me first answer you.

Mr. BILIRAKIS. Yes.

Mr. CHAN. The goal is achieving 90 percent level of vaccination and the current time when it's set is for basically——

Mr. BILIRAKIS. That's your 90–96 year?

Mr. CHAN. Right, by 1996. There are different ways of looking at it and I think we had some discussion with CDC about this.

One is that you can look at it and say if the outcome you want is prevention of a specific disease or outbreak, then you can look at the level of immunization for measles or DTP or polio.

From that perspective what I was reporting is that as of May, 1994, which is the last time they had the statistics on, they have reached the level of 91 percent for MMR; for DTP–3 that means three shots of that, it's level was at 90 percent; for OPV–3 it's in the neighborhood of 80 percent; for DTP–4 I think it is 70 percent,

so if you look at that from that perspective, the disease prevention approach, then we are really, you know, late in 20 percent—this is for children under two—20 percent in DPT–4 and as well as OPV, 10 percent for OPV for the third shot.

Mr. BILIRAKIS. Okay. Now what is keeping us from increasing those figures and proving those figures to the 90-plus category?

Mr. CHAN. Well, the way I see the problem is that we're designing a program trying to solve something we call "90 percent solution" to a 20 or 10 percent problem. In that sense, you already have people achieving a pretty close goal and that's why we raised the question, you know, it's my own personal belief that even if we reach 90 percent there is no way for us to say that disease would be prevented in an outbreak anywhere because essentially you can still have, as Mr. Towns said, an area such as the inner city where the immunization is really low and all you need is someone to bring the disease and then you have an outbreak.

Mr. BILIRAKIS. Well, my time, sir, has expired and I don't want to be unfair. I'll shift over to Mr. Waxman.

Mr. WAXMAN. Thank you, Mr. Chairman.

Mr. Chan, right now under existing law the States have the responsibilities to oversee the immunization of the children the State, isn't that right?

Mr. CHAN. Yes.

Mr. WAXMAN. And this Vaccines for Children program didn't envision taking that responsibility from the States but helping the States by providing less expensive or in fact often free vaccines so the States wouldn't have to spend their money on the vaccines.

Mr. CHAN. Exactly, yes.

Mr. WAXMAN. And the idea behind the legislation was then to say to the States that appropriated moneys of the Federal Government to help the States could then be used for outreach?

Mr. CHAN. Yes.

Mr. WAXMAN. I think it is important to recognize that the idea was not only to provide supply but the idea was to look at it in a context of having the supply there and the outreach and that ultimately the State had to mesh these two together.

Now your testimony states that cost is not a major barrier to children's timely immunization. You also cite studies showing that cost is less important than other barriers. But you are not saying that cost is not a factor at all in any case, are you?

Mr. CHAN. Well, I would say that it is not possible for anyone to say cost is not a factor at all. Cost has to have some factor in it.

The question is, is VFC addressing cost? If you believe cost is a factor then you design the system——

Mr. WAXMAN. But my question to you——

Mr. CHAN. [continuing] to address that.

Mr. WAXMAN. My question to you is in designing a plan, you are not saying we shouldn't consider the cost as one factor that can be a barrier to kids getting immunized?

Mr. CHAN. Yes, okay.

Mr. WAXMAN. Okay, now your testimony notes that implementation of the VFC program remains incomplete. In light of the complexity of scope of this program, isn't it a bit too early to declare

its implementation a failure? Shouldn't we give a program of this nature at least 1 or 2 years of experience before we scrutinize it to determine whether it has passed or failed?

Mr. CHAN. I don't think in our testimony we have actually given it a grade. What we have said is six out of seven functions they still haven't been fully implemented after 9 months. If in fact the CDC says that as of the year 2000 it will be fully implemented, then my answer is it hasn't been so, but you still have time.

It's really what you are targeting for.

I think the general gist of our testimony is that there are problems going on in terms of implementing this program and then the other message we are trying to get across, is that we have much more concern about these pockets of needs and we want to raise that while that is, you know, being sort of neglected.

Mr. WAXMAN. Well, I agree with you that we don't want to neglect these other factors.

Mr. CHAN. Exactly.

Mr. WAXMAN. Because they are very important and in fact they may be the most important factors.

There's a lack of understanding, especially by a lot of the immigrants that come to this country about the importance of getting their children immunized. There is a cultural way of looking at things where they don't bring their kids in.

School entry is a good nexus point because then people are told you must do it or the kids can't get enrolled in school. But now we are looking at a major sea change in health care in this country for low income people.

You indicated that a lot of immunizations have taken place but you have to admit that a lot of those immunizations have taken place because Medicaid paid for it.

Now we are looking at the possibility that Medicaid may not pay for it. We may not have a Federal role any longer because we are going to send money to the States and say here's your block grant, do all that you need to do under Medicaid—serve the elderly, take care of kids, take care of the disabled.

You are critical of this program because of the lack of accountability but wouldn't you say that if we just gave a block grant to the States and said take care of all these problems there would be even less accountability as to how they are doing with immunizations?

Mr. CHAN. Well, let me try to give you my own perspective, how I see this program, okay?

Pre-VFC Medicaid children are included in there. All other people including uninsured can go to public clinics for shots? Post-VFC the only difference I see is that the uninsured population, which consists of 25 percent of that, will now be able to go to private physicians to get the shot. Forget the finance for the moment. That's the population that you add on. Otherwise, even for the uninsured under VFC they are not to be administered in the private physician's—they still have to go to the public clinics, so that is how I see this program.

Mr. WAXMAN. Just to conclude——

Mr. CHAN. I'm sorry.

Mr. WAXMAN. [continuing] I want to make this statement.

I see what you are saying but my concern is now that we go from here, we are not talking about going back to where we were. We are talking about going further back than that. We are talking about eliminating the Medicaid responsibility and block granting the funding for it, we are talking about making inadequate funding available for these clinics. So I think that this critical evaluation of a program that has only been in effect for 9 months is going to be used by people who will say, well, let's just throw the whole thing out. Then we are not going to be in the pre-VFC era. We are going to be even in worse shape and that is what I fear.

Mr. CHAN. I see.

Mr. BILIRAKIS. Thank you, Mr. Waxman.

Mr. Klug.

Mr. KLUG. I would like to commend the three of you for your fine work on this study and the work you did earlier last year.

Mr. CHAN. Thank you.

Mr. KLUG. Let me just ask you a couple of simple questions if I can.

Can you tell me how much money we spent so far on this program?

Mr. CHAN. I can't.

Mr. KLUG. But what is the approximate amount?

Mr. SHARMA. We have asked for some detailed information from CDC that we have not obtained.

Mr. KLUG. I'm sorry, they can't tell you how much the program cost?

Mr. SHARMA. We had requested this information at your request from CDC but we have not received detailed information about what the total cost has been.

Mr. KLUG. So you don't know the cost of the program? You have no idea?

Mr. SHARMA. What we can tell you is what it has been. As Mr. Chan indicated that the cost for vaccine is about $425 million and it's about $45 million for the administration but beyond that we don't have any, at least at this point, detailed information.

Mr. KLUG. So they have not to this point supplied you with a number that says here is what we have spent? That's correct?

Mr. CHAN. No, we have not received that.

Mr. KLUG. Well, but then assuredly they have been able to give you numbers of how many more children they have immunized?

Mr. CHAN. Well, no, they can't either because as I said the last estimate they came out with through a survey is in April-June timeframe, which is before VFC is in place.

To specifically answer your question——

Mr. KLUG. To make sure I understand this, we have set up a new entitlement program for which presently we have absolutely no cost estimates and then second we have no idea whether there has been a single new child immunized as a result of it?

Mr. SHARMA. We asked CDC these questions and they could not tell us whether as a result of VFC a single kid has been immunized or not. It's not to say that they have not been immunized, but CDC cannot tell us.

Mr. KLUG. But this is a program frankly that has had trouble with numbers all along, and I want to take you back to some of

the battle again over statistics about the need for this program or the problems with measuring just how severe this is.

When the program was originally rolled out, the administration suggested that there were some fairly dramatically low numbers of children who had been immunized, in the 60 percent range. Does my memory hold true?

Mr. CHAN. I think it was 40 to 60 as stated by——

Mr. KLUG. Then subsequently have you discovered how old those statistics may have been that they were using?

Mr. SHARMA. I think they were using the late 1980's statistics at the time—there is one point that I want to make is there are two ways to look at those statistics.

One is to take a look at in terms of the up-to-date immunization for the basic series, which is 4–3–2–1.

Now if you take a look at the statistics this way, there is a potential to deflate the statistics for the following reason. They are saying that a kid requires four shots of DTP and if the kid got three shots of DTP he is considered the same way as a kid who got zero shots, so when you pool them together what you see is a much lower number, but from a disease prevention point of view what you really need antigen-specific rates and if you take a look at it that way, what you find is, what your target is for some specific vaccines you need to intervene and include the immunization rates and then the number is within 20 percent range, which is the lowest number.

Mr. KLUG. Well, give me some examples of what our goals that were laid out in this program initially might have been and perhaps where we are today if you took a snapshot of the antigen rates?

Mr. SHARMA. Well, as we've indicated in our testimony and report that for two of the antigens we have already reached the 90 percent goal. For other two vaccines we are near the goal and if we really need to, this is an area where we need to concentrate, which is about less than 10 percent, but if you pooled them then you would not get the same picture. You will be talking about 70 percent of the kids have not been fully immunized as opposed to 10 percent.

Mr. KLUG. But using that analysis that you did, which obviously suggests we are much closer to those original numbers, I mean we essentially have an entitlement program in place for which we don't have a financial estimate, correct?

The CDC at this point can't produce any evidence for this committee which says how many more children have been immunized, finally, for a program which I take it we have already reached many of the goals that we are spending this $450 million to accomplish.

Mr. CHAN. Can I? Congressman Greenwood mentioned about the 1993 hearings and Secretary Shalala presented some statistics at that time and the statistics presented for comparison against other countries, and the year that they used was 1985.

Mr. KLUG. Excuse me, they were 1985?

Mr. CHAN. Yes.

Mr. BILIRAKIS. Please finish up, Mr. Klug.

Mr. KLUG. Thank you, Mr. Chairman. I have no other questions.

Mr. BILIRAKIS. I thank you, sir. Mr. Wyden.

Mr. WYDEN. Thank you, Mr. Chairman. I want to commend all of you for your excellent work, and we have worked closely with you on that for almost 2 years on this and I think my friend Scott Klug has hit a central question.

The program was fogged in pretty early and that was what your first audit said and we are still seeing that we can't get basic questions answered about, you know, who, when, where, and the nuts and bolts of implementation, and I find this particularly difficult because I am somebody who believes that there is something in between the extraordinary inefficiency you all are pointing out and just sending a check to the States and saying, here, best wishes, hope everything turns out and the kids get immunized—I think there is something in between and I want to ask you about a couple of issues that I think can help us find that approach.

Now we are almost concerned about the needy youngsters and you already told Mr. Klug that CDC doesn't really have a handle on how many of them are getting immunized.

Do they have, in your view, management systems that will be capable of telling us at some point whether these needy youngsters, the so-called pockets of need, that those needy youngsters are being served?

Mr. CHAN. The way they determined the level of immunization is through surveys and one is the NHIS survey, and the second is random digit dialing through telephones. There, one can reach a particular, specific area like through dialing and obtain information about them. But we don't have information on specifically the underserved population——

Mr. WYDEN. So you believe their management systems as they stand today are not capable of telling Congress the most important information, which is the data about the needy, is that correct?

Mr. CHAN. That's correct. Did you want——

Mr. SHARMA. No, that is correct. What you need is rapid accessment techniques, which they don't have.

There are two things, with the current statistical system they have, they do not tap into those pockets of need. Random digit dialing is the closest system that they have, but they do it at the metropolitan area not by a zip code and you'd need to have that kind of information.

Second, the current accountability mechanisms they have would not allow them to know which kid got vaccine, so they would not know, to answer your questions on pockets of needs.

Mr. WYDEN. In terms of a accountability, what ideas can you give us in terms of our discussions with the States that could actually put in place some accountability so that when the Federal Government works with the States we can have some assurance that these youngsters get served?

Mr. CHAN. Do you want to answer?

Mr. SHARMA. We have discussed this issue with State officials and also with a lot of physicians in private practice.

In principle, physicians have said to us two things. They are very skeptical of the Federal Government because any time there is an entitlement program there is a lot of paperwork requirements and CDC has responded to and listened to them, and as a result of that

they had very little paperwork requirements. The second message that we got from the physicians is that they don't mind reporting to the Federal Government as long as the system is simple—it matches with their existing system needs. That is, in order to get reimbursed, most physicians currently have to submit claims to the insurance company, which is a proof, a record that they got immunized, and if CDC could design a system that will capture this information without duplication, physicians would have no objection to it.

Second, at least in some States through CDC's own initiative they have now come out with a registry system where all physicians do report.

Mr. WYDEN. So there are some models where we cold have accountability through the kind of physician reporting that you are talking about and at the same time it wouldn't be bureaucratic water torture? It works and there is evidence that there are models, is that right?

What States are those? My time is up.

Mr. SHARMA. Mississippi is one, I'm told.

Mr. WYDEN. Okay. If you could furnish that to the subcommittee, because I think that is one of the things we have got to have is some accountability and I appreciate your response.

Thank you, Mr. Chairman.

Mr. BILIRAKIS. Thank you, Mr. Wyden, and would you please furnish that to the subcommittee within the next few days?

Mr. SHARMA. Yes.

Mr. BILIRAKIS. All right, thank you. Dr. Coburn.

Mr. COBURN. Thank you. Can you explain for this committee the statement that Mr. Stupak stated in terms of the significant cost in rise of vaccines for children that are immunized now? I think it was from $30 or $60 to $260. Can you explain the reasons behind that for this committee?

Mr. CHAN. Yes. I don't have exactly the statistics in my head but I think they are caused by a number of things.

One is that of increased number of new vaccines being introduced and the second is that the schedule would increase in terms of number of doses you need, and third is the insurance——

Mr. COBURN. Is it not true that the addition of one, Hepatitis B, added greater than $150 to the cost of immunizing children on those pre- and post-statistics? Is that not true?

Mr. CHAN. It could be, yes. I don't know the numbers exactly though. That's why I can't——

Mr. SHARMA. Let me just add, you know, the increase that has been cited has many factors including the fact that new vaccines has been added that has been—the Vaccine Compensation Act has taken care of some of it.

There were some liabilities issues and so on and so forth.

Mercer Group, which is going to be appearing in front of you shortly, has done some very systematic analysis and has essentially concluded that for the most part prices have remained stable.

They increased in the 1980's but if you controlled for the inflation, then I think——

Mr. COBURN. So it's probably the increase in antigens and the increase in frequency and dose that's——

Mr. SHARMA. That's right.

Mr. COBURN. And this program when it was sent out to the States, did it have strings attached to it that the States had to meet, guidelines that the States had to do to participate in this program?

Mr. CHAN. The State had to do?

Mr. COBURN. Yes.

Mr. CHAN. Well, as I said before, the States are to take over the issues of accountability, guidelines to enroll private providers and as well as doing evaluations on the program.

Mr. COBURN. Would it make sense to you that if the States were responsible for immunizing and also responsible for controlling epidemics and also responsible for the ultimate costs through their Medicaid program of epidemics of childhood diseases, would it not make sense to you that they would have a great interest in trying to increase immunizations?

Mr. CHAN. Yes.

Mr. COBURN. Is that not logical? So that in fact if States were responsible for immunization programs and had the funds, whether it be block granted or directly and had the best interest of their own State's well-being, both financial and health, you would want to summarize it that they in fact would probably aggressively try to immunize their children?

Mr. CHAN. Oh, there's a lot of evidence of that. We did our survey and there is a lot of ideas that they have.

Mr. COBURN. All right. Thank you very much. I have no additional——

Mr. BILIRAKIS. I think the gentleman's time has expired. Mr. Stupak.

Mr. STUPAK. Well, thank you, and thank the gentlemen for appearing today and your testimony.

Let me ask you this. We talked a lot about cost but let's talk a little bit about direct and indirect costs.

Would you agree with the CDC that immunization of children with the current DTP, HIB, measles, and polio vaccines is cost effective and is saving us money in both direct and indirect costs to our general economy?

Mr. CHAN. Yes. I think a lot of research has been done showing the cost benefit of vaccination. There's no question about that, you know, talking about 20, 30 to 1 ratios type of numbers.

Mr. STUPAK. So for direct costs it is about 10 to 1, isn't it, for every dollar we spend for immunization we save 10 in health. In indirect costs it is about 25 to 1.

Mr. CHAN. Depending on the disease, yes. It's tremendous. I think there's no question about it's doing the most effective thing in terms of preventive health care.

Mr. STUPAK. The cost of immunization, that is one of the factors in preventing people from being immunized, is it not?

Mr. CHAN. Well, I think as we stated before it's not one of the major factors because the evidence really suggest that when they do have to immunize, they do immunize, so therefore the under-immunization, the word itself I think suggests something else.

To us, we use "timely immunization"—there's a delay in it, that's all.

Mr. STUPAK. I'm a little confused with your testimony because on May 4 before the Senate Finance Committee there were four experts who testified, you being one, and three of the four agreed that cost is a major barrier to a successful program.

In fact, Mr. Chan, you said that—if I can quote you—you agreed "Cost is a barrier to immunization." Those were your exact words then. Today it seems like you are going a little back on that testimony.

Has something happened between May 4 and——

Mr. CHAN. No. We just see it as a barrier. All the available evidence suggests that it's not a major barrier because it's sort of like, you know, it is a barrier in terms of payment, but I think what we are trying to explain is that the VFC is a program that addresses only partially the cost of immunization and we have stated in our previous statement that the amount of money you spend in the vaccine itself versus the office visit versus the administration itself, it's much greater than the immunization of—I mean the cost of vaccine itself.

So in a way that is one part of the total cost.

The second thing is, for the population we are talking about the only additional group we are adding is the uninsured children being able to get free vaccine but still have to pay administrative fee and office visits in the private provider's office, otherwise everything would be the same.

Mr. STUPAK. When you talk about these costs and effectiveness of the program, then go back to my first question. If it's about 35 to 1 this is a pretty cost effective program then.

Mr. CHAN. Yes. And we stated that last time too in our testimony, sir.

Mr. STUPAK. Thank you. I have no further questions——

Mr. WAXMAN. Would the gentleman yield, please?

Mr. STUPAK. Yes, I would yield. I would yield to Mr. Waxman.

Mr. WAXMAN. Mr. Chairman——

Mr. CHAN. In terms of immunization I think I mentioned, yes.

Mr. WAXMAN. [continuing] if we have a block grant for Medicaid and we shrink and maybe even eliminate the appropriations that go now to the vaccine program at the Federal level and we leave it solely up to the States, wouldn't you expect that the price of vaccine costs are going to rise to the States because the Federal Government won't be a central purchaser, giving the States that lower price for vaccines?

Mr. CHAN. We see, I think, in the 317 money spent that CDC did negotiate with——

Mr. WAXMAN. No, my question to you is if we do away with the VFC program, we shrink the appropriations under whatever the other section is that we have had in the past because we are on this glide path to a deficit—to a balanced budget, and we turn over the program to the States with a block grant sum of money, that would mean no Federal purchasing of vaccines to help the States lower their costs for the immunization program.

Won't that mean that States are going to have to come up with more money to pay for vaccines and will have less money to do outreach?

Mr. CHAN. Mr. Waxman, I think I will let the politics to take care of what will be included or not included because I really don't know how much money would be put in and so on, in terms of, you know, the purchase of vaccine or the infrastructure.

Mr. BILIRAKIS. The gentleman's time has expired.

Mr. Greenwood.

Mr. GREENWOOD. Thank you, Mr. Chairman. You have covered some of this ground but I want to read a quote from the hearing that I referred to back in April 1993.

I was trying to get the Secretary, Secretary Shalala, to focus on the notion that it would be much more sensible to put some requirements in front of WIC, AFDC, and so forth. Again, she reiterated that it wouldn't solve the problem because she said 60 percent of the children whose families are over the poverty line don't have their vaccinations before they are 2 years old.

I know you have responded to this once, but this isn't the case, is it?

Mr. CHAN. Sixty percent?

Mr. GREENWOOD. Sixty percent is a quote from Dr. Shalala—60 percent of the children whose families are over the poverty line don't have their vaccinations before they are 2 years old.

Mr. CHAN. I don't know where she got that data from. We couldn't find it.

Mr. GREENWOOD. That was not an accurate statement, was it?

Mr. SHARMA. I guess the point, what we have heard, is there are two things, for what year's statistics she was using and whether they were the most current statistics at the time, and second is whether the statistic she has presented is for update on the basic series, kids who had all four shots, and if you, as I explained to you earlier, if you use those statistics they could be somewhat misleading in the sense that it deflates the antigen-specific immunization rates, so I am not questioning about the fact that whether 60 percent or, you know, 70 percent. That's really not the issue.

Mr. GREENWOOD. For any of the gentlemen, what do you think would happen if the Congress and/or the States said that a requirement of participation for children in the WIC program, the food stamps program, or AFDC, is that they have their proper immunizations at the appropriate time.

What do you think it would do in assisting us to resolve this issue, compared to what has been done in the last couple of years?

Mr. CHAN. I think there are a number of programs being introduced in various States trying these incentives, sort of the carrot-and-stick approach and, you know, the results have been highly effective.

We include that one portion of our finding in our report showing those kinds of effectiveness.

Mr. GREENWOOD. Can you quantify how effective some of those programs have been?

Mr. CHAN. I'm sorry——

Mr. GREENWOOD. Do you want to vote?

Mr. SHARMA. In some of the programs, for example, dates have gone up as much as 30 to 40 percent. In others, you know, gone up as much as 60 percent and these are all studies. They have doc-

umented this. Maryland is one example where they had tremendous success.

CDC's own research has funded several such projects and most of these research show great promise.

In particular, coordination with large public programs such as AFDC and WIG has been found to be very, very effective and there are some requirements placed as a condition for participation.

Mr. CHAN. I think in regards to the four diagnostic studies we mentioned earlier they found that if one can just address missed opportunities by the providers, physicians themselves, you have about as much as 15 percent increase in immunization rates.

Mr. GREENWOOD. Well, tell me if you agree with this statement: 2 years ago some of us said that there are real problems in poor neighborhoods that are identifiable, and if we put gates on these programs, we'll be very, very successful in immunizing children. The administration said well, no, that's not the case because even when we look at children over the poverty level, 60 percent of them don't have their shots. That would be an ineffective way to go at the problem. So, they went off on their course, which is what we face today.

Now, is that pretty much what has happened here?

Mr. CHAN. Well, I think the logic is that if 60 percent of the children in the over poverty then I would target the program to address those problems, but this is sort of a universal approach to solving the problem and I think it's hard to account for it as to where is it effective.

Mr. GREENWOOD. The whole program has been based on a faulty set of assumptions, wouldn't you agree with that?

Mr. CHAN. Yes.

Mr. BILIRAKIS. The gentleman's time has expired.

We have a vote so we will break until approximately 12:25. Thank you.

[Brief recess.]

Mr. KLUG [presiding]. We are going to resume so that what is now the lunch hour doesn't disappear into the dinner hour.

Mr. Towns actually has the right to ask questions on the other side of the aisle if and when he returns, but in the meantime let me ask my colleague from North Carolina, Mr. Burr, to ask questions.

Mr. BURR. Mr. Chairman——

Mr. KLUG. He is recognized for 5 minutes.

Mr. BURR. At this time I am going to yield back on my questions to speed up the process just a little bit.

Mr. KLUG. Mr. Whitfield.

Mr. WHITFIELD. I yield back my time as well.

Mr. KLUG. And they yield as well. Now we're moving. I would like to thank the folks from the General Accounting Office for the fine work they have done in this program.

I just wanted to ask one question of clarification. Mr. Stupak earlier asked you a question about whether or not the vaccination program was cost effective, at which point I think you answered yes.

But I think there's really two questions there. Is vaccinating children cost effective because of health care, or is this program in and

of itself cost effective. So how about splitting those two questions up and answering them more directly.

Mr. CHAN. Well, I think you are right that in terms of vaccination, as I said before, there's a lot of research showing that it is very cost-effective to vaccinate children in terms of reductions in morbidity and mortality.

From the VFC program itself I think if the interpretation is that my answer is that it is. The best way for me to answer this is to read my final paragraph, which I was unable to state earlier.

In our statement it says, "Based on our findings the Congress may want to consider refocusing VFC's goal from the improvement of general immunization rates to achievement of high immunization rates in pockets of need where conditions are ripe for diseases outbreak among under-immunized children. A program with immunization targeted to pockets of need should be more cost-effective than the current approach in conjunction with enrollment, accountability, automation and evaluation effort needs to be adjusted to focus on children who are at the greatest risk for delayed immunization.

Mr. KLUG. Thank you for clarifying that.

Mr. CHAN. Okay.

Mr. KLUG. And just when we thought that we were out of questions then Mr. Ganske has now returned. Dr. Ganske had several questions for you.

Mr. GANSKE. Thank you. I just want to summarize here. You have basically three main conclusions to your study, if I am correct:

First is that the cost of vaccines hasn't been a major barrier. Second, even a fully functional VFC is not likely to prevent outbreaks of disease. Third, the data on under-immunized children in major metropolitan areas indicate that supplementary action independent of making the vaccine free may actually hold more promise.

As I look over the rest of your report it is fairly critical of the organization and the administration of this program.

I mean you talk about vaccine contracts, problems with vaccine distribution, provider enrollment, order, processing, accountability and evaluation—all the things that you would normally do with a GAO report.

What assurances can you give the committee on the validity of your study, the accuracy of your study?

Mr. CHAN. Well, let me first say that the three points you made to summarize what we tried to say is absolutely correct.

On the second question, when we did our first study, May, 1994, we looked into these seven areas as primary areas that for this program to be successfully implemented they need to be resolved because they are inter-related. That is, if you don't enroll the providers then, you can't distribute and if you don't settle the cost side in terms of administrative costs and ultimately you don't have accountability in terms of potential misuse and waste of the vaccine that is shipped to you, those are issues I think that we were raising.

Now not only have we talked with experts, in terms of experts we talked with a panel who did physical diagnostic studies. We brought them together and spent time and addressed those so-called barriers of not achieving timely immunizations.

We did two separate surveys across all 50 States in terms of the implementation status and we completed the last one as of March 1, 1995.

We did another survey in the handling of the VACMAN, which is the computer that links the vaccine purchase together.

We spoke with manufacturers about their concerns including studies being done by the Mercer Group and then asked them about the studies they have done.

When we finished as of 30 May we had our exit conference with CDC and gave them our general findings and they gave us feedback and I think unfortunately because of time limitations we were only able to give CDC a day and a half or so of time for them to read our draft report and give us comments.

I think what we tried to do is tried to present the data as objective as we can and hopefully we have done that.

Mr. GANSKE. Some people would argue that some of the points that you have brought up do not necessarily argue against the program but could argue for improvements in the way the program is administered, but I get the feeling from reading your report that you feel that the fundamental premise that the program is based on, that is, that the vaccine cost is the reason why we have low vaccine rates in some areas, is just not the correct premise in the first place. Is that your basic finding?

Mr. CHAN. That is correct.

What we did is the way I would like to examine this issue, you know, what is the nature of the problem, and then what is the solution that is being used to solve that problem and we find that there's basically a mismatch and I think your observation is correct.

Mr. GANSKE. Thank you.

Mr. KLUG. Thank you, gentlemen. You are excused and I appreciate all of your help.

Mr. CHAN. Thank you.

Mr. KLUG. Our next panelist is Dr. David Satcher, the Director of the Centers for Disease Control and Prevention in Atlanta.

The CDC is the Agency responsible for the implementation and operation of the Vaccines for Children program.

Dr. Satcher, I would like to thank you for taking the time to testify before this committee today. I know you have a lot to say, but I would appreciate it if you would keep your opening remarks to 10 minutes, please.

Mr. SATCHER. Ten minutes. Thank you.

STATEMENT OF DAVID SATCHER, DIRECTOR, CENTERS FOR DISEASE CONTROL AND PREVENTION; ACCOMPANIED BY JOSE CORDERO, DEPUTY DIRECTOR, NATIONAL IMMUNIZATION PROGRAM

Mr. SATCHER. As you pointed out, I am David Satcher. I am Director of the Centers for Disease Control and Prevention. I have with me Dr. Jose Cordero, who is the Deputy Director of the National Immunization Program. Dr. Walter Orenstein, who is the Director of that program, is out of the country in Israel and is not able to participate in this hearing.

I have submitted a complete statement for the record and will summarize that statement.

Let me say that for us the business of immunization is very serious business. We believe that there is no more significant medical intervention than the immunization of children. We believe that it is, in fact, cost effective.

Our impressions related to the value of immunization and the value of this program are based on years of experience at CDC, not only with immunizations in this country but throughout the world and even today the World Health Organization looks to the CDC for leadership in an effort to eradicate polio and other vaccine-preventable diseases throughout the world.

Let me say that one of the real problems with the discussion today is that the Vaccines for Children program is one part of a comprehensive five part program, the Childhood Immunization Initiative. If Vaccine for Children is discussed in isolation, we miss that fact and we reach the wrong conclusions. The Childhood Immunization Initiative is a bold initiative to remove barriers to immunizations in this country. It is a bold initiative to empower States and to empower local communities. It is an initiative to empower parents and providers. It is about an ambitious goal. It is a goal to eliminate childhood vaccine preventable diseases by assuring that by the year 1996 children are fully immunized by the age of two for the initial and critical vaccines and by the year 2000 fully immunized for all of the available vaccines.

Let me take a minute and point out the elements of the Childhood Immunization Initiative. There are five, not one. The VFC is only one of them.

The first part of that initiative is to work with States to improve the quality and quantity of vaccine delivery systems and that includes improving clinic hours, improving the role of nurses and nurse practitioners, physician assistants, and others in providing vaccines to children, helping communities to organize. Some of the innovative things that you have discussed in terms of providing incentives grew out of that program that was funded by the CDC. It was a part of this initiative.

A second part of this initiative is to make sure that research continues in terms of developing new vaccines and new vaccine packaging programs, so we support research and development. We believe that without it we would not reach our goals. We have to continue research.

A third part of the program and probably the one that has been in some ways most successful and most recognized is the outreach program. There is a very comprehensive nationwide outreach program to educate parents, to motivate parents, to educate providers about the importance of immunization and to help develop community programs to make sure that children are immunized.

A fourth part of the program is very important to providers. It includes developing registries so that if at any time a child comes to a physician's office and the physician doesn't know where the child is on the immunization schedule, that physician will be able to call up a State-based registry and to find out where the child is on the schedule. Parents will also know because the system al-

lows for automatic generation of information saying to parents your child needs another DTP or your child needs immunization.

That is four parts of the program and I have not yet mentioned VFC so let me mention VFC. We do believe, even as GAO says otherwise, that cost is a barrier. We believe it is a significant barrier. We believe that it is a tragedy for a physician to have to refer a patient in his or her practice to a public health clinic in order to get immunization. That is the way in which cost is a barrier because many physicians are being forced to do just that.

Let me say where I think we are in operating this program, which is still a very new program. As Congressman Waxman pointed out, it is operating in all States. The purchase contracts were signed in September despite the fact that an earlier GAO report said that we would not be able to get the contracts signed. They were fully signed by the end of September.

State health departments are enrolling public health providers in all States and the enrollments of private provider sites now are in the tens of thousands.

The vaccine ordering system is in fact working, not because we say it is working but even the Logistics Management Institute, contracted through the Department of Defense, evaluated the ordering system and said that it is in fact working well.

There have been 2,400 bulk orders to date, processed for the purchase of 19 million doses of vaccine.

But let me point out that the Vaccines for Children Program has not been trouble-free. It involves the implementation of new legislation, new Federal-State relationships, and new public-private partnerships. This implementation has caused problems. We are not yet satisfied with the accountability programs. We are not yet satisfied with the evaluation. But we do believe that we are headed in the right direction in giving the States the responsibility for these initiatives.

Our partners, by the way, are profoundly supportive of this program. The overwhelming majority of States in this country are supportive of this program and that includes California, that includes Wisconsin by the way, it includes Georgia, South Carolina, Delaware, on and on. We have statements from States all over the country saying how important the Vaccines for Children program is and how it is working in their States. We would be very happy to share that with you.

In addition, private physicians' organizations, including the American Medical Association, the American Academy of Pediatrics, the American Academy of Family Physicians, and several others, all say that the Vaccines for Children program is the right approach to help solve this problem of under-immunization. This support includes non-Governmental organizations, and you will hear from some of them today, like the Children's Defense Fund.

We are disappointed in the GAO report because, while it makes some very important points and we are looking forward to working toward resolving those problems, we believe that it ignores the support and testimony of Partners.

We believe that GAO did not give an adequate opportunity for CDC to respond and I think that is a major flaw. If you are evaluating a program that CDC is running I think you should respect

the input of CDC and give adequate time for CDC to respond, and that response should be included in the report.

GAO did not in fact talk to the major front-line people.

We know that cost is a barrier. GAO has said this before and even though GAO says it is not a major barrier it doesn't say how much of a barrier, it is.

Well, let me say that there has been a tenfold increase in the cost of vaccines in the last 10 years. All over the country people tell us that is a barrier. Many of the parents are working parents. They work every day. They support their families. They don't have insurance coverage. They do want their children to be immunized and they want them to be immunized in the physicians' offices where they have primary care.

Several studies show that high cost is forcing pediatricians and family physicians to refer patients.

In 1992 the American Academy of Pediatrics showed that 55 percent of pediatricians had increased their referrals of patients to public clinics. Since that time the State of North Carolina did a study showing that 93 percent of pediatricians and family physicians were referring patients from their offices, from their practices to public clinics for another visit in order to get immunization—and I am a primary care physician.

For a primary care physician to have to refer a patient out of his or her office in order to get immunization is something that should be totally unacceptable to this Nation

Parents can choose to keep their children in their medical homes because of the Vaccines for Children program. GAO fails to understand and to elucidate that the basic purpose of the VFC is to allow this to happen. GAO fails to elucidate the relationship of the VFC program to the larger Childhood Immunization Initiative, the five part comprehensive incentive.

Before I close I want to make one last and critical point.

Children need 11 shots before their second birthday. The bottom line is there are about 2 million children in this country who are not being appropriately immunized by the age of 2.

To immunize them by the time they enter school is not early enough.

At the age of 2 I almost died from pertussis, long before I was ready to go to school. I was 2 years old—so the question is not can we get children immunized before they enter school at 5 or 6. The question is can we get them immunized by the age of 2.

We must do our part to do that.

Let me close by saying there is no more cost-effective program than immunization.

For every dollar that we spend on measles, mumps and rubella, we save $21.

For every dollar that we spend on DTP, we save $29.

For every dollar we spend on polio vaccines, we save $6.

But let me take it a step further. What's happened since a very comprehensive effort with smallpox resulted in eradicating smallpox from the world——

Mr. KLUG. Dr. Satcher, I am not trying to rush you, but——

Mr. SATCHER. Yes, I have another minute.

Mr. KLUG. That's fine.

Mr. SATCHER. What's happened is that we now save in excess of $500 million a year because we don't have to immunize against smallpox or to have a quarantine system. What will happen when we have eradicated polio from the world because of a comprehensive program? We will save at least $230 million every year in this country when we have eradicated polio from the world, and $1 billion a year will be saved globally.

[The prepared statement of David Satcher follows:]

PREPARED STATEMENT OF DAVID SATCHER, M.D., PH.D., DIRECTOR, CENTERS FOR DISEASE CONTROL AND PREVENTION

Mr. Chairman, I am Dr. David Satcher, Director of the Centers for Disease Control and Prevention (CDC). Thank you for the opportunity to appear before this Committee to discuss childhood immunization. This is an issue that is near and dear to my heart. As a child, I was stricken with whooping cough and learned from my own experience that the diseases we are trying to prevent are truly excruciating to children.

As a doctor, I have worked with children and families that have tried to cope with the preventable tragedies of diseases like polio, mumps, and measles. And as the Director of the Centers for Disease Control and Prevention, I have been truly impressed with the expertise, experience, and commitment of the immunization leaders in my agency and around the country. The CDC has some of the finest health professionals in the world on our team—and it is a privilege to call them my colleagues.

I am here to tell you about the progress we have made since February, 1994, when President Clinton's Childhood Immunization Initiative was launched, and since October 1, 1994, when the Vaccines for Children (VFC) program became operational. I am especially pleased to have the opportunity to set the record straight with respect to issues that have been raised by the General Accounting Office (GAO), regarding barriers to immunization, and the successes and problems of implementing the VFC program.

THE CHILDHOOD IMMUNIZATION INITIATIVE

While the focus of today's hearing is on the VFC program, we must remember that the program is one important part of a sustained, comprehensive strategy to reduce the incidence of childhood infectious disease. Recognizing that there are multiple barriers to preschool children's immunization, the Administration with Congress, the CDC, the States, health care providers and other partners, developed the Childhood Immunization Initiative (CII) to increase and sustain immunization coverage rates.

The CII is designed to marshall efforts of the public and private sectors, health care professionals and volunteer organizations. Our goals are to reduce most vaccine-preventable diseases to zero; increase vaccination levels for 2 year-olds to at least 90 percent for the initial and most critical doses by 1996; and establish a sustainable system to ensure that at least 90 percent of all 2 year-olds receive the full series of vaccines by the year 2000.

The Initiative includes five interrelated strategies to address the many difficult reasons why children do not receive their immunizations. We are working to: 1) improve the quality and quantity of vaccination delivery services; 2) reduce vaccine costs through bulk purchase contracts for the 317 and VFC programs; 3) increase community participation, education, and partnerships, through local, state, regional and national outreach efforts; 4) improve the monitoring of disease and vaccination coverage by enhancing our disease surveillance and immunization registries; and 5) conduct cutting-edge research to improve vaccines and vaccine use. Taken together, these five strategies will put in place a sustainable system to protect our youngest and most vulnerable Americans.

We are making excellent progress towards our goal of immunizing 90 percent of the nation's children against vaccine preventable diseases. In fact, our most recent immunization coverage data, from the second quarter of 1994, indicate that not only are we at record high levels of immunization coverage for all the needed vaccines, but we have just achieved a 90 percent vaccination level for DPT3+. As I have stated previously before the Senate Finance Committee, I believe if we stay focused we will achieve our goal.

However, we still have work to do. Our data tells us that about 500,000 to 1.9 million of our nation's children between 19 and 35 months of age still had not re-

ceived recommended vaccinations against specific diseases. As noted in the table below, about 2 million of these children had not received the full series of vaccinations and about 1.2 million had not received necessary polio vaccinations.

Table 1—Vaccination Levels and Estimated Numbers of Two Year Old* Children Not Fully Protected in the U.S., 2nd Quarter 1994

Vaccine	Vaccination Levels (Percentages)	Estimated Numbers of Children Not Fully Protected
DTP 3+	90	600,000
DTP4	70	1,700,000
OPV 3	80	1,200,000
MMR	92	500,000
Hib 3+	76	1,400,000
4DTP/3OPV/1MMR	68	1,900,000

*Children 19-35 months old.
Note (1): A "+" next to a vaccine indicates 3 or more doses. For example, DTP 3+ is receipt of 3 or all 4 recommended DTP doses.
Note (2): Hepatitis B, although a recommended childhood vaccine, is not included in the table. The coverage for Hepatitis B was only 29%, leaving 4.1 million children not fully protected. However, many of these children were born before the Hepatitis B recommendations were in effect.

SUCCESSES IN THE VFC PROGRAM

The VFC Program is important for several reasons: It improves access to vaccines for our neediest children and working families; it allows eligible children to obtain immunizations in their medical homes, rather than having to go to a public clinic; and it is forging new public/private partnerships to get more children immunized.

The VFC Program began a little over 8 months ago, but we have already reached a number of impressive milestones:

- VFC is operating in all States.[1]
- Vaccine purchase contracts were signed with the manufacturers to provide vaccines for eligible children at discounted CDC contract prices for all vaccines routinely recommended for children.
- State health departments have enrolled, or are enrolling almost all public health providers, including public health department clinics, community health centers, and other public facilities.
- Across the country, tens of thousands of private health providers have been enrolled. We expect to increase the enrollment of private providers as more States develop systems to deliver vaccines to private providers.
- The vaccine ordering system is working well. Over 2,400 bulk orders have been processed, and almost 19 million doses of vaccine have been shipped to public and private providers.

A cornerstone of the VFC Program is the forging of new partnerships with private providers. Support from public and private medical communities at the National, State and local level have strengthened our efforts to immunize children.

The major private physician associations have expressed strong support for the VFC program. CDC has made it a priority to solicit the views of these groups and tailor the VFC program to meet their needs and concerns.

By purchasing vaccines at discounted CDC contract prices State governments benefit. Before the VFC was implemented, the Medicaid program often paid the higher private sector price for vaccine, about $265 for the total series—a cost shared by State Medicaid programs. The discounted CDC price is about $118. Now, children served by Medicaid can receive free vaccines through VFC providers, and States do not have to share the purchase price with the Federal government. This program saves millions of dollars for State Medicaid programs, freeing up resources for other urgent needs.

Most State Health Departments strongly support the VFC program and value its benefit to individual children and communities. Several States, including California, Georgia, Oregon, South Dakota and Rhode Island, have reported to the Association of State and Territorial Health Officials that, without the VFC program, their immunization efforts would suffer catastrophic consequences. Some States, such as Connecticut, Kentucky, Idaho, and Michigan, advised they would have to limit the

[1] Alaska, which already delivers vaccines to all providers in the State, is not participating in the VFC program. Alaska is able to use other Federal vaccine funds to purchase all vaccines for all children in the State.

availability of some vaccines, including the *Haemophilus Influenzae* type b and Hepatitis B vaccines, and South Carolina reported that immunization rates would plummet.

While some private physicians fear that the VFC will increase their paperwork burden—which is not true—we expect continued increases in enrollment. This will occur as more States establish delivery systems to private providers, and as the facts about the operation and benefits of the VFC program are more widely recognized.

The VFC program has strengthened and institutionalized the partnership between public and private medical communities at the National, State, and local levels. Many medical professional associations, representing private physicians, support the program and are working with us to implement the VFC program. These groups include the American Medical Association, the American Academy of Pediatrics, the American Academy of Family Physicians, the American Osteopathic Association, the National Medical Association, and the Interamerican College of Physicians and Surgeons.

CHALLENGES WE FACE IN THE VFC PROGRAM

The implementation of the VFC program has not been trouble-free. Implementing complex, new legislation never is—and in this case we have only had about 8 months since the kick-off of the program to iron out all the wrinkles. But we are well on our way to surmounting every hurdle.

That said, we believe the recent GAO report on the VFC program is deeply flawed. Quite frankly, the GAO misunderstands the premise of the VFC program and as a consequence misrepresents its current achievements and future benefits.

For the record, I would like to state that we are not in agreement with most of the criticisms found in the GAO report. Moreover, we are dismayed that CDC was provided a single working day to review the report and provide GAO with our response to its findings. Despite our best efforts to convey our concerns, it is my understanding that the GAO did not give us enough time to include a response in their final, printed report.

COST IS A BARRIER TO IMMUNIZATION

Perhaps the single greatest flaw in the GAO report is that it fails to recognize the basic premise of the VFC program—that children need a medical home for all of their healthcare, including immunizations, and that the high cost of vaccines is a barrier to children being immunized on time in their medical homes. GAO fails to acknowledge the large body of research literature documenting this fact.

The literature shows conclusively that the high cost of vaccine causes at least two adverse outcomes. First, parents often defer having their children immunized at the right time and instead wait until they reach school-age. Second, parents are referred routinely to overburdened public sector clinics, which further contributes to missed opportunities for all clinic patients.

The cost of the vaccine series has increased about ten-fold in the past 12 years. There are a variety of reasons for this increase: the addition of new vaccines and additional doses of existing vaccines to the series, excise taxes, and some increase in the cost of the old vaccines. When parents must pay about $265 in vaccine costs to have each child fully vaccinated, it stands to reason that many families who lack adequate insurance will seek immunizations from public health clinics where the vaccine is free or far less costly, rather than go to their private doctors. Unfortunately, having to make the extra visits to public clinics can delay the timely immunization of children.

Before the VFC program was introduced, numerous studies documented increasing immunization referrals from private doctors to public clinics, primarily because of the high cost of vaccines. A 1992 American Academy of Pediatrics study, revealed 55 percent of pediatricians refer some or all of their patients for immunizations to a public provider. A 1992 North Carolina survey documented 93 percent of physicians referred patients to health departments for immunizations. And, in a 1993 survey of 538 families attending public immunization clinics in California, Lieu and colleagues concluded that financing reform has the potential to improve vaccination rates if it is combined with improved parent education and reduced non-financial barriers to immunization.

Studies also show that referrals from doctors offices, cause delays in immunization of children. Zimmerman and colleagues documented this fact in a study of about 500 children served by private physicians in Minnesota. It was shown that the average age of children at the time of immunization varied according to their insurance status. For example, for the third dose of DTP, which is scheduled at 6

months of age, insured children were vaccinated at an average age of 7.8 months, children with no insurance were vaccinated at 11.6 months of age. That is almost a 6 month delay in protection beyond the recommended schedule. For MMR, which is scheduled at 12-15 months of age, insured children were vaccinated at an average age of 17.8 months compared to 20.9 months for children with no insurance. The study also showed that children with no insurance were more likely to be referred to public clinics (68 percent) compared to fully insured children (0 percent). These results document, consistent with other studies, that children without insurance are very likely to be referred for immunizations and that these referrals may produce delays in the receipt of vaccines.

Finally, while there has been some disagreement regarding the extent to which vaccine cost poses an impediment to age-appropriate immunization, experts agreed recently at a May 4 Senate Finance Committee hearing that cost was a barrier. During the hearing Chairman Packwood asked witnesses if cost was a barrier. Despite very different backgrounds, experiences, and opinions of the VFC program, three of the four witnesses answered that cost was a barrier. Dr. David L. Wood, of the Cedars-Sinai Medical Center in Los Angeles noted that cost, "...adds to the problem..., It adds to their (providers) reluctance to give vaccine, to be as aggressive about giving vaccines as we need providers to be." Dr. Lloyd F. Novick, the first Deputy Commissioner of the New York State Department of Health noted "Cost is a problem in New York State. There are other problems, but cost is one of the problems."

I want to note, the goal of the VFC program is not just to provide free vaccines to children as an incentive for their parents to have them immunized. Rather, the goal is to make cost-free vaccines more readily available in children's medical homes—their doctors' offices. By doing that we will protect more children, improve children's health by keeping them in their medical homes, reduce the burden on public health clinics, and free up scarce public health resources for states and communities. The Vaccines for Children program is crucial to our overall approach to protecting all American children. It is this crucial role of the VFC in the Children's Immunization Initiative that GAO has thoroughly failed to understand. I would now like to address some of the specific criticisms of the GAO report.

Enrollment

CDC is monitoring the enrollment of providers into the VFC program. As I noted earlier, we have enrolled almost 9,000 public health clinics and over 23,000 private provider sites many with multiple physicians per site—in the VFC program.

We have given the highest priority to implementation in public clinics, where about 50 percent of the vaccines in the country are administered. These clinics traditionally serve those populations most in need of timely immunizations and are located in critical geographic areas.

A few States have decided not to enroll private providers until a private delivery system to these providers is established. Because the absence of a delivery system in some States may cause providers to wait to enroll, we expect to increase the enrollment of private providers as the few remaining States complete implementation of their delivery systems.

CDC is conducting a national private provider immunization study to hear from practicing pediatricians, family physicians, and osteopathic physicians who provide immunizations to children under 5 years of age. This study will provide information on physicians' practices that will help CDC to enhance enrollment efforts.

Computer Ordering Systems

CDC made the correct priority decisions to have an effective ordering system functioning in a safe and timely manner to meet legislative requirements. All 50 States and the District of Columbia are effectively using the system and have placed over 2,400 bulk vaccine orders. Had the CDC employed the formal analysis procedures suggested by the GAO, instead of the informal approach we used, ordering would have been delayed well beyond the October 1, 1994, legislatively mandated start date.

Our vaccine ordering system was implemented effectively and efficiently by building on an existing system. Logistics Management Institute (LMI), an independent group of experts in logistics and data systems, reviewed the VFC system and concluded it is effective and meets the program's needs.

CDC did analyze software and other requirements but did not have time to formalize these analyses of systems requirements, alternative systems cost benefit analysis, risk analysis, or security and disaster recovery. LMI has found that CDC had "taken steps to assure that data and systems files are systematically backed-

up. Recovery, should failure occur, would in our opinion be relatively quick and inexpensive."

By January 1995, CDC completed technical systems documentation for disaster recovery plans, security, and systems and risk analysis. To a large extent, these documents represent the documentation of analyses for which GAO was looking.

Existing hardware at the State level was inadequate to support VFC ordering requirements. For example, there was insufficient memory on the older computers for VFC software, and the hardware could not prevent the loss or rapid transmission of data.

CDC used an existing contract to purchase hardware and commercial software at substantial savings. At a cost of less than $10,000 per immunization project, or a total of about $500,000, these systems include standard components, including data security systems, identical to that being used in corporations and by private users. LMI found "hardware and software reliability to be the equivalent of similar commercial applications and sufficient to implement the VFC program."

Significant enhancements have been implemented as the system has matured that allow data to be appropriately exported to other State computer systems and allow software to operate on the States' various Local Area Network environments. CDC is continuing its needs analysis to coordinate the ordering system with other data systems.

Vaccine Delivery

In September, 1994 CDC began negotiations with vaccine manufacturers for the delivery of vaccines to private physicians. We recognized at the time that agreements would have to established with all four vaccine manufacturers in order for a delivering system to be viable. On April 10, lacking the prerequisite agreements with all four vaccine manufacturers, CDC had to discontinue these negotiations.

CDC immediately inaugurated efforts to provide for State-based, private sector delivery systems. VFC vaccine is being delivered now to tens of thousands of public and private providers. Forty-nine States are delivering vaccines to public clinics and 39 States have informed CDC they are delivering vaccine to enrolled private providers. The remaining States report that they plan to begin delivering vaccine this year or early next year.

CDC met with States in mid-May and again on June 9 and will complete discussions with vaccine manufacturers, private provider organizations, and wholesale distributors by mid-July to determine how best to assist states in delivering vaccine to enrolled private physicians.

Administration Fees

Fee caps were initially established based on "usual charge" data provided by the American Academy of Pediatrics. These fees are maximums and do not necessarily reflect the charges that will actually be passed on to patients. In fact, participating providers are required to agree that no one can be denied vaccines due to inability to pay fees.

HCFA has undertaken a study to estimate actual provider costs and expects to base future fee caps on these costs by the end of the calendar year.

Accountability

In building an effective accountability system, several activities were undertaken, including the development of State accountability plans, monitoring orders, and the submission of provider profiles to States by enrolled providers.

States have the primary responsibility to ensure that VFC (and 317) vaccine is used appropriately. States have over 30 years experience managing immunization programs and are in the best position to account for these vaccines. This approach is consistent with the goal of empowering States to manage program processes as long as outcome targets are met through performance measures.

CDC has contracted with Battelle to evaluate accountability systems in six pilot states. We are making site visits to States, we are presenting accountability options to State Health Officials and public and private providers, and we are evaluating State vaccine ordering patterns.

It is crucial to maintain the right balance between effective accountability and accomplishing overall program goals. If providers had to report each immunization transaction, they would be burdened with filling out and sending in over 14 million pieces of paper a year. That would be a waste of their time and a disincentive for busy health professionals to participate in the program.

Indeed, when we solicited the views of private provider organizations they warned us that excessive paperwork would prevent physicians from enrolling in our program. Also, the HHS Inspector General has just released a survey of several hun-

dred physicians that found excessive paperwork could discourage them from participating in the VFC program.

Program Evaluation

It is difficult to evaluate the VFC program independently because there are difficulties in isolating immunization variables, such as education or infrastructure improvements. Nevertheless, we are working with evaluation experts to develop a comprehensive VFC evaluation plan. CDC believes baseline information can be obtained from retrospective studies, thereby allowing for comparisons of pre-VFC coverage levels with coverage after VFC.

HISTORICAL PERSPECTIVE

At the beginning of my testimony, I stated that if we continue our comprehensive and intensified efforts, we will achieve our goals. Conversely, any significant disruption to this country's commitment to childhood immunization will return us to an era of continued epidemic threats.

The evidence is clear. Over the years, after funding for immunization has decreased, disease incidence among children has increased. For example, after funding for measles immunization decreased in 1968 and 1969, cases tripled between 1969-1971. After funding decreased from 1974-1976, cases more than doubled between 1975-1977.

On the other hand, when Federal funding for immunization increases, disease levels decrease. For example, funding was increased from 1970-1972, and measles cases had decreased by 65 percent by 1973. Before cutting immunization funds, we should reflect on these patterns.

Promoting childhood immunization must be viewed as a national priority that requires Federal/State partnership. Why is a strong Federal role so important? Quite simply, if one State provides inadequate funding or support or makes poor decisions about immunization policy, and an outbreak of disease results, residents of other States are threatened. In fact, vaccine-preventable diseases do not respect State borders, particularly in an era like this one when so many Americans move from State to State.

To illustrate my point, let me tell you two chilling stories about multi-State outbreaks of measles that occurred in 1994. In one, a child from Colorado was exposed to measles while playing in a children's arcade in Las Vegas. The child returned to Colorado and spread the disease, which resulted in three generations of new measles cases before it was finally contained. Vaccine cost alone for this outbreak was at least $150,000. In another, also in 1994, a chain of measles transmission began in Breckenridge, Colorado, and spread into nine additional States. A total of 247 cases was reported, representing 36 percent of all U.S. measles cases that year.

CONCLUSION

Preschool immunization represents one of the most, if not the most, cost-effective public health interventions. However, vaccines can only be as effective as the system we have to make sure that preschool children receive them on time. There is no single solution to meet this national challenge. No one approach addresses all the different barriers faced by the preschool population. We believe that we can reach our goals only with the sustained implementation of our current comprehensive strategy.

This country has too often merely responded to public health crises rather than preventing them. If we are to prevent infectious childhood diseases, we must build a comprehensive vaccination system that is secure and sustainable—not only for today's children, but tomorrow's as well. This system must function well not only during and immediately after an epidemic, such as occurred after the recent measles resurgence of 1989-1991. Rather, the system must work during those periods when infectious diseases seem to ebb and parents' fears of childhood diseases have subsided. For it is during those times when parents and providers are most at risk of being complacent, and complacency is the enemy of protecting children's health.

The CII is designed to build a permanent immunization system by enhancing vaccine delivery infrastructure, reducing cost as a barrier, building local partnerships, mobilizing communities to protect children, enhancing State data systems to help parents and providers remember when immunizations are due, and much more. The CII is a major step forward in improving the health of our children, and CDC is committed to the full implementation of this Initiative.

Mr. KLUG. Thank you, Dr. Satcher. And we will guarantee that your full statement is put in the record.

Let me start off. You indicated in your profession that cost is still a major barrier, but if cost is a major barrier, why is it that we've achieved immunization levels well above 95 percent when children are five, but we haven't when they're two? Assuredly, it is just as expensive for parents of 4 year olds as it is for 18 month olds.

Mr. SATCHER. Let's make one thing clear. When parents get ready to enroll their children in school, different States have guidelines for what's required, and in many cases what you see are people lining up at public health clinics to, in some cases, get one shot in a series like DTP, because that is all that is required in order for the child to get into school.

We're not talking about that. We are talking about completely immunizing children at the age of 2 so that they don't get illnesses between 1 and 5. So let me say to you that we're not talking about the same thing.

Mr. KLUG. But if cost is a barrier at 2 it should be a barrier at 4. The difference is that there is a requirement for the parents to do it at 4.

Mr. SATCHER. Cost is not the only barrier. We make that very clear, and that is why I pointed out to you the five points of this initiative. Cost is a very important barrier. There is a different situation at entering school.

There is not the requirement of all 11 vaccines. There are State requirements in terms of what it takes to get into school.

Mr. KLUG. The GAO indicated in its testimony that there were four studies done for the Center for Disease Control and Prevention that were never published that essentially rejected the central thesis of this entire program that cost is the major barrier. Do you agree or disagree with GAO?

Mr. SATCHER. I totally disagree. Those four studies looked at four different cities in terms of what happened in public, and, in some cases, private encounters. It started with Medicaid patients. Basically, what it pointed out was what we've said before, cost is not the only barrier. Even for people who have Medicaid, there are barriers because there are some private physicians with Medicaid who would prefer not to purchase the vaccine under Medicaid and wait 6 to 9 months to get reimbursed.

But the point of that study was not to say that cost was not a barrier. It was to say that we need to define other barriers that result in children not getting immunized when they see physicians even if they have Medicaid. We are trying to deal with that in a comprehensive program.

Mr. KLUG. Why not simply take this money and give it to the States and say if you need to spend it to buy shots, do it; but if you want to hire more public health nurses, do it; if you want to keep clinics open late at night; do it.

Why is it that we've essentially targeted $450 million already only to do one thing when even you admit that's not the only thing that stops kids from being immunized?

Mr. SATCHER. Right. And I don't want to get into the politics of this, but I will give you my opinion about the $450 million.

We spend right now $120 billion every year treating infectious diseases. It is a very good investment spending $450 million and more to immunize. In fact, one of the major problems we're facing

in this country today is, even when we treat children with antibiotics, many of the organisms are becoming resistant.

So if you have a choice between immunizing children and preventing infection as opposed to spending $120 billion a year to treat infectious diseases, then I don't think there is any comparison.

So from our perspective, the immunization program is a very good investment, and I would think it would be ridiculous not to implement it fully.

The second thing I want to say is when it comes to the States, I think this is a Federal/State relationship. I don't believe that there is any other example that we have before us that is a better working relationship between the Federal Government and the States.

Now, on the one hand, GAO is criticizing us for not micromanaging at the State level; we don't want to micromanage this program. We want the States the manage this program and we want to support them.

Mr. KLUG. May I read you a letter from the State of Maryland dated February 10, 1995, "Dear VFC Provider, we have found serious problems with overestimates of eligible children. The combined estimates of eligible children from the currently enrolled VFC Maryland Provides indicate there are 185,000 eligible children under the age of one, or twice the number of children born in the State of Maryland every year."

Mr. SATCHER. I think there are still problems at the State level. You just illustrated a State level problem, and there are problems at the local level, and there are still problems at the Federal level in terms of issues of eligibility.

I mean, there is a very confused system when it comes to who is eligible for what.

This program was intended to try to deal with this problem. I think the State of Maryland has done a good job in many ways. I think the incentive program is an excellent one, so I am not knocking that, but that statement doesn't take away from the validity of this program.

Mr. KLUG. You are indicating there is a well-defined partnership between the CDC and the States, and here is a letter from a State saying the regulations and guidelines are so confusing they've essentially double counted all the kids born in the State.

Mr. SATCHER. I don't think Maryland was saying that was a CDC problem. I think you're misreading that.

Mr. KLUG. My interpretation is different than yours, obviously.

Mr. SATCHER. Yes. CDC does not define eligibility, because the legislation defines eligibility.

Mr. KLUG. My time is up, and I will stay on the schedule to give my colleagues an opportunity to ask you questions. I may come back and follow-up some more.

Mr. Waxman?

Mr. WAXMAN. Thank you very much. Dr. Satcher, we just heard from the GAO a recommendation that we re-target VFC funding to pockets of need throughout the country based on the fact that under immunization tends to occur primarily or exclusively in very specific identifiable areas. Do you agree with this?

Mr. SATCHER. No, I don't. I think as long as you have over 30 percent of the children in this country not being appropriately immunized by the age of two, you have a nationwide problem, and it is not just a problem for the children who are not immunized; it is a nationwide problem.

That is why we spend some time and effort in Sub-Saharan African and South East Asia with the immunization program, because we realize that it is a global problem when people are not immunized.

Once we get to the 90 percent immunization level, and that is a strategy here, then more effort would be toward targeting those pockets of need but not when you have 32 percent of children across the country not appropriately immunized.

Our goal is to get 90 percent of children fully immunized. Then people ask, well, what about the other 10 percent?

Well, most of our studies suggest that once you get the 90 percent then your focus can be on targeting pockets of need.

Mr. WAXMAN. This question of cost. GAO seems to rely quite heavily on the fact that they think cost is not that much of a factor.

You are a physician yourself and you've talked to other physicians. What is your view of the relative importance of cost compared with other factors that influence whether children are immunized or not?

Mr. SATCHER. I think cost is very important, and that is what we hear from physicians who practice in these communities. As some of you know, I started my career in the Watts community, not only practicing there, but while a Clinical Scholar at UCLA did an extensive study on what the barriers were to access to care. That was published in 1980 in the Journal of Family Practice, and very clearly showed that working parents especially who could not afford insurance, but who wanted to have private physicians viewed, No. 1, immunization as the most important aspect of health care.

No. 2, the most important thing was to be able to go to your own family physician or pediatrician and get that service, and all other primary care services. Anything that prevents a parent from having a relationship with the physician, and that physicians being able to provide comprehensive primary care to his or her patient is not only important, it is critical, and that is what the VFC program attempts to address.

Mr. WAXMAN. We've heard arguments that the VFC program costs too much and is not cost effective. Would you please tell us exactly how much you're spending on this program this year, and describe for us the payoff in terms of the cost savings associated with the immunizations that are provided with the funds under the program.

Mr. SATCHER. Well, in 1994 we spent $572 million total, not for the VFC, but for the section 317 program, including $193 million for vaccine purchase. In addition, a total of $270 million was spent for Medicaid vaccine purchases. Medicaid was then not able to get the vaccine at the contract price. States spent another $109 million in 1994 before the VFC program started.

We estimate that in 1996, when all of the Medicaid program is under VFC, we'll spend about $365 million for vaccine purchase for the Vaccines For Children program. States will continue to spend

$109 million. We will also continue to support State's vaccine purchase infrastructure with $165 million. That's about a 12 percent increase from 1996 over 1994.

And the reason that there is such a small increase even with making a new program available is by bulk ordering and negotiating at the discounted Federal vaccine contract price, we're able to get the vaccines at a lower cost.

States are benefiting tremendously from this because they don't have to, therefore, pay for the Medicaid vaccine price component. So the States are benefiting from this program.

But the interesting thing is that we're talking about a 12 percent increase after this program is fully implemented in 1996.

Now, as times goes on there will be new vaccines, and one of the beauties of the VFC program is that it encourages research because companies know if they produce new vaccines there will be a way of paying for them.

So even though there are problems with research and development, and I certainly am concerned about that, there are also incentives in this program for that.

Mr. WAXMAN. Let's say we took this program and put it in a block grant of Medicaid. Can we assure ourselves and everyone else that the chicken pox vaccine or other new vaccine—that we'll know that there will be a national commitment to immunizing children?

Mr. SATCHER. No, I don't think we can. I think States have had real problems. They've had real problems with the Medicaid program. They've implemented it at different levels. I don't believe a Nation can afford to leave something as important as immunization as a burden for States in isolation, and I don't believe the States feel that way.

My impression is that, not only on a national level but an international level, we have a responsibility when it comes to immunization. It is just like protecting your water so that you don't have, as we had in Milwaukee in 1993, 400,000 people getting infected with cryptosporosis. That's a Federal problem. It is not just Milwaukee's problem. We can't afford to have a water supply system in this country that is not safe. We can't afford to have children that are not immunized because it is not just that State's problem.

If a person gets measles, a person in the next State can get measles. We've have several examples of that. We had an outbreak in Las Vegas. Before it was over, people in Colorado and California and elsewhere had measles from this outbreak.

So we are not talking about an isolated State problem; we're talking about a national problem, and there has to be a national approach, and I think States agree with that.

Mr. WAXMAN. Thank you very much.

Mr. KLUG. Thank you.

Mr. Burr?

Mr. BURR. Thank you, Mr. Chairman. Dr. Satcher, let me say that we certainly respect the work of CDC. I think what we are here debating today is how we increase the level of immunization in children versus whether we immunize children.

I just want to set that straight. Certainly, I would be one who would vote for CDC maybe to look at military procurement and other things if, in fact, we have become that proficient at purchas-

ing drugs, because it will be the first thing that I've found that the Federal Government actually would negotiate the best price versus the private sector.

Let me head in a different direction for a second. You, in your testimony—and I'm on page 2 of your written testimony—you talk about the initiatives included in five interrelated strategies to address many difficult reasons why children do not receive their immunization. One, improve the quantity and quality of vaccination delivery services.

How many children, based upon that strategy being implemented, are immunized?

Mr. SATCHER. I'm not going to play games. I don't think anybody can answer that question. You can pretend or GAO pretends that if you launch a nationwide strategy that a few months later you can tell somebody exactly how many children have been benefited.

There is no program in this country where you can do that.

I think what we can do is survey populations, and over a period of time we can look at the outcome of comprehensive strategies. I am not going to pretend that we can dissect out every strategy and say for a given strategy how much this part had in it and how much that part had in it, and I don't think we have the facilities to do that in any program in this country.

But I do think we can monitor what is happening to children, and we can look at different States and different localities, and we can see if we're making progress.

We can also compare strategies because some States, as you pointed out, have initiated one strategy. Like one State had their clinics open at night. Another State even used the National Guard, for example, and this comes under that initiative that you just described.

Mr. BURR. Understand, Dr. Satcher, what I'm trying to do as an individual is determine how CDC judges success in immunization.

Mr. SATCHER. Well, I'd be happy to answer that question.

Mr. BURR. Let me go a little bit further, if I could, because I was going to ask you on all five of the initiatives that you've set up because you've said they are crucial.

Let me just go to the end of the paragraph. It says, "Taken together, these five strategies were put in place a sustainable system to protect our youngest and most vulnerable Americans." I guess my question would be if you can't gauge the steps individually of their success based upon an immunization number, then can you tell me what basis you use to reach that conclusion.

Mr. SATCHER. Let me make sure, Congressman, that I'm clear.

I did not say we could not gauge the steps. You said could I tell you how many children are immunized. I don't think that is the only way to gauge the steps, and I speak as—I think most public health experts would agree——

Mr. BURR. Let me go back to a GAO conclusion, and you tell me whether you disagree with that.

Mr. SATCHER. Okay.

Mr. BURR. One of the conclusions of their study was that in most cases we were above or close to the 90 percent goal of immunization prior to the implementation of VFC.

Mr. SATCHER. If you break down the antigens individually, there are some where we are much further along than others. Those are our data, by the way. CDC is the organization which provides those data. We don't hide them.

We don't think there is anything wrong with the fact that if you look at just three shots of DTP, you get a much higher figure, close to the 90 percent, than you do if you look at all four, or if you look at polio and just having two oral polio, it is much higher than all three.

We have over 20 percent of children in this country who are not fully immunized for polio by the age of 2.

But you are right. If you break it down, you will find that for two individual antigens (HMR and DTP–3) we are at 90 percent.

Our goal is for all of the several antigens that are appropriate by the age of two, we will be at 90 percent by the year 2000, and by the year 1996, for all the critical ones, we would be there.

Let's give an example. We have introduced a new vaccine in 1988. We've fully introduced hemophilus influenza b. In the short time since 1988, we've had a 90 percent reduction in meningitis and other brain damage associated with hemophilus influenza; 20,000 children a year were contracting hemophilus influenza, many of them getting meningitis. We've had a 90 percent reduction.

We can tell you that. We can tell you the impact of these vaccines. We can gauge, as you put it, the impact. We may not be able to count the number of children in every local community, but we can gauge the impact of introducing a comprehensive strategy, and that is what we do.

Mr. BURR. I see my light is up. Let me say certainly my attempt, and I think the attempt of the committee, is to determine what you use as that gauge of success so that we can determine whether the program is, in fact, headed in the right direction.

There are certainly conflicts. One of the things that we are required by the people who elect us is to account for money and to come up with specific numbers of progress so that we can relate to them how successful they are.

Mr. SATCHER. May I say that we would like to work with you. If you think that we're not using the appropriate strategies for gauging the success of these programs—and we've called in a lot of experts—but we would be happy to sit down with this committee or anybody you would want to have sit with us and look at our strategies for gauging.

I agree with you, we have to be accountable. We take accountability very seriously. If we're not doing it correctly—it is true that we have invested a lot at the State level. We did not want to micromanage this program, but we do want to have accountability. So we would be willing to work with you.

Mr. BURR. Dr. Satcher, just a follow-up, quickly. Is there a tremendous difference between you turning a program over to the State and not micromanaging and our doing that?

Mr. SATCHER. When we turn it over, we turn it over while maintaining the Federal responsibility in terms of things like trying to make sure that the program goes in the right direction. That doesn't require micromanagement.

I think the overall responsibility for immunization in this country is a Federal responsibility because there is no State that has contained within its borders the problem of vaccine preventable diseases. As I gave you the example before, we have an outbreak in one State and several States are affected. There are many examples I could give you.

So there is no one individual State that has this problem unto itself. It is a national problem.

Viruses and bacteria don't need visas, even across national boarders, let alone State borders. This is not a State problem.

Mr. KLUG. Mr. Wyden?

Mr. WYDEN. Thank you very much. Doctor, I am very pleased that you are here. You make many points on which I agree. Obviously bugs don't stop at State borders. We have to deal with public health concerns as they come up.

As a CDC supporter and as a CDC supporter for a long time, three things have come up recently that have chipped away, frankly, at the confidence I have of CDC. This Wall Street Journal story of a couple of days ago where your own people, as part of an internal review, talk about series management problems at the Agency. It concerns me very greatly.

One of your people says that 318 positions that have been audited, the initial findings show that grade levels and salaries of 86 positions can't be supported. These are your folks.

Mr. SATCHER. Congressman, let's make sure that we quote the study correctly. That study came from 1992 and 1993 when CDC geared up for taking care of AIDS and immunization. What is happening now is a process of reclassification to correct that problem. That problem is not a recent problem. It grew out of gearing up to deal with AIDS and immunization.

The people who you are quoting are talking about an outcome of an Office of Personnel Management study that was done in 1992–93.

I happen to have been president at Meharry at the time. I take the responsibility very seriously for solving the problem, but I don't want you to say that it is a new problem that has been defined by the Wall Street Journal recently.

Mr. WYDEN. Clearly, your people say it is a current problem. I mean, they quote a CDC official and I'm not talking about 3 or 4 years ago. It says microbiologists can't get equipment because CDC has been paying some people $45,000 a year for secretarial work.

Mr. SATCHER. Staff were placed in those positions is when—they were placed in those positions during the effort to gear up to deal with AIDS and immunization. You can't get Federal people out of positions in 1 day, so the process of reclassification has been going on for a while.

You're quoting Jack Jackson, and he's absolutely right, but I think you're misunderstanding what he's saying. The salary decisions were made when we geared up for AIDS and immunization, and he says that.

Mr. WYDEN. We'll make the article a part of the record, but a combination of this article would certainly to me—and I think to any reader it would suggest that there are these problems currently faced by the Agency.

Yesterday I was informed that the Agency has no intention to implement the fertility clinic law that I authored in spite of the fact that we've got these problems in Orange County and elsewhere.

Finally, the management problems that the GAO has raised, as I said, chip away at the confidence of a supporter of the CDC like myself.

My first question on the vaccine issue specifically is that the CDC told us that as much as 30 to 40 percent of the under immunization problem could be dealt with if doctors only gave appropriate shots during regularly scheduled office visit with the needy youngsters. They said that in one fell swoop we can deal with close to half of the problem.

What is CDC doing within the context of the VFC program to address something like this?

Mr. SATCHER. Well, the VFC program is a part of a comprehensive strategy. We believe that part of the reason that children don't get immunized when they go to their physician is, in fact, cost. We've made that very clear.

But we don't believe that is the only reason, so we are working very closely with States to develop registries so that if a physician has a patient, the physician may not know where the patient is in the immunization schedule and the parents also may not know. We're trying to put in place in States the necessary information that would be readily available. We think it would make a big difference.

We've also educated physicians, by the way. There are still physicians who believe that if a child has a fever that maybe they should not be immunized.

CDC conducted a program last year where about 15,000 providers participated. It is the largest program in 10 years to update physicians and nurses and nurse practitioners and physician assistants in the immunization schedules. So I think we have accomplished——

Mr. WYDEN. I would like to get one other question if I could, Mr. Chairman, and doctor, I support your effort with the registries, and I think that is constructive.

The other management failure that particularly concerns me is that the GAO said in response to questions from Congressman Klug and myself that while it was not possible today to determine how many youngsters had been immunized and whether the needy youngsters were being served, they said—and I think this is especially important—that the Agency didn't have management systems in place to be able to tell Congress down the road whether needy kids were being served.

What is your response to that comment?

Mr. SATCHER. My response is two fold. We're not happy with the management systems in place. We have invested that primary responsibility in the States. As you've heard GAO say, there are at least, I believe, eight States where we feel they are models.

We are going to move forward with those models. We brought on experts, Batelle and others, to work with the States to improve the accountability system. We believe that there is a need to improve

accountability. We believe we are moving in that direction after 8 months in this program.

Mr. WYDEN. My time is up. I just want you to know that as a CDC supporter, the kind of things I've heard from the Wall Street Journal, fertility program, now from the vaccine program today raise some serious questions in my view about the Agency's ability to tackle these type of problems.

Mr. SATCHER. Congressman, let me express my appreciation for your support for CDC. I think if you have questions, we ought to get answers to your questions. All I ask is for you to give us an opportunity to answer them.

Mr. KLUG. Speaking of questions, Mr. Whitfield.

Mr. WHITFIELD. Dr. Satcher, I also want to welcome you here today. Many of us on this committee are new members, and we're delighted to have someone with your expertise to help walk through these programs.

I wanted to touch on a couple of things. You mentioned earlier that there are about 2 million children in the United States who have not been immunized. Can you tell me if they are located in primary areas of the country or how did you come up with this 2 million figure, and what is the distribution of those children?

Mr. SATCHER. They are scattered throughout the country and it is true that there are areas where they are more concentrated than others. For example, inner city communities. There are inner city communities where less than 50 percent of children have received the full course of immunization.

I think you heard Congressman Towns say he felt that in some areas of New York there may be only 11 percent of children had been fully immunized. We don't have that data. We're working very closely with New York State and the City of New York. I think New York State is one of the strongest supporters of the VFC program, however.

Mr. WHITFIELD. But of the 2 million that you've identified, you don't have this broken by State or by city?

Mr. SATCHER. The survey is a survey that is done nationwide. We can target cities. We can in fact target cities and tell you where any given city is. We have to work with the State and local community to do that. We have done that in many cases and can give you that information. We haven't done it for every city in the country.

Mr. WHITFIELD. But you can do it by State pretty easily?

Mr. SATCHER. Sure. We have data from just about every State regarding where they are with immunizations.

Mr. WHITFIELD. Out of this 2 million, how many would you say would be in the State of California, for example?

Mr. SATCHER. I think I can say with some help from my colleagues pretty quickly where we are in the State of California. I know it is a significant number based on the population and the immunization levels.

Mr. CORDERO. We don't have the numbers here, but we can provide those to you.

Mr. WHITFIELD. Okay. Now I'm assuming that these 2 million children are from depressed areas, primarily from low-income families. Would that be a fair characterization?

Mr. SATCHER. Many of them are. I do want to point out that we are talking, to a great extent, about working families. Working parents who may not be able to afford insurance, but they do have private physicians, they go to those physicians.

Dr. Burtcher from California, who is in San Diego and who is the former president of the National Medical Association, talked about how the Vaccines For Children program had benefited him because now that he doesn't have to worry about the cost of the vaccine, it is not his concern if the parents can't pay him to administer it.

He wants to keep those patients in his practice. He is willing to provide those vaccines free of administrative costs. And that's what we've said. We've said that in order for a physician to participate in a program, the inability of the parents to pay for the immunization cannot be a barrier to getting the vaccine.

Mr. WHITFIELD. So prior to the program most of these children, would it be fair to say, receive their immunization through Medicaid? Would that be accurate?

Mr. SATCHER. Many of them didn't receive it at all.

Mr. WHITFIELD. But if they did receive them, it would have been through the Medicaid program, right?

Mr. SATCHER. Yes, I think about half of the children who would benefit from this program at least are on Medicaid.

Mr. WHITFIELD. And as I told you before, one of the real problems with Medicaid—and I don't want to go into that in detail—is that there are many physicians with whom I've worked for the last 12 years who won't see Medicaid patients for various reasons. There are others who see them, but they have to buy the vaccine up front, and then they have to bill Medicaid to get reimbursed, and it takes various periods of time for that depending on where you are in your situation.

I know there are a number of differences, but one of the major differences you think would make this program more effective is the fact that you all do the bulk buying of the vaccine and distribute that so that it is not a cost factor for the physician that administers it? Is that correct?

Mr. SATCHER. Right. And the other point, and I think you're making this point, is that we believe that it is critical that parents be able to get their children immunized in their physicians' offices. We don't believe they should have to schedule another appointment at a public health clinic, and we don't believe that physicians who don't want to should have to send their patients away from their practice to get something as important as immunization.

Mr. WHITFIELD. One other question.

Mr. KLUG. Mr. Whitfield, last question.

Mr. WHITFIELD. Okay. You indicated earlier that this program is actually an incentive to drug companies to be involved more in research and development. How is that possible when you put a cap on their price?

Mr. SATCHER. That is a very important question. One way that this is an incentive—and what we've heard from some of the manufacturers is that we now know when a new drug is developed—within the context of this program, that drug can be paid for, and so many manufacturers agree that aspect of the program is, in fact, an incentive.

Now, there are some other disincentives that we do need to talk about, and I believe that to the extent that cost is a disincentive, then I think we ought to sit down and deal with it.

Dr. Lee, the Assistant Secretary for Health, by the way, has written the manufacturers pointing out our desire to really work with them around the research and development issue.

Mr. WHITFIELD. Thank you.

Mr. KLUG. Dr. Ganske?

Mr. GANSKE. Thank you. First I want to say that I think the CDC does great work in the areas where it has expertise, but I think that the administration and distribution of medical supplies is probably not one of those areas, and that has been pointed out by the GAO report.

The CDC-sponsored studies show that most of the under vaccination among groups who already have access is in the groups where there is already access to free vaccine, kids who are enrolled to Medicaid or have had access to public health clinics. Many of them have been to their physician multiple times, so they've had opportunities.

For one reason or another—and I'm sure you can give me those reasons—they don't get the vaccine. Some of it is probably related to the fact that they are coming in to see the doctor and they have a febrile illness, and maybe it isn't an appropriate time to give a vaccine.

What I want to ask you is would you be in favor of tying the receipt of welfare benefits to compliance with immunization?

Mr. SATCHER. Let me go back because it is important that I make one thing clear if I misstated it. A child coming into a doctor with a fever is not a reason not to give a vaccine. That is one of the major things we have been trying to communicate because that was one of the causes of missed opportunities, that misconception.

I believe that missed opportunities—and it was, in fact, CDC research that demonstrated the missed opportunities—I think there are missed opportunities because of misinformation, I think there are missed opportunities because the physician doesn't have the information about where the child is on the schedule, and the parents often don't know where the child is, so we miss opportunities, and our programs are designed to deal with those.

And we believe there are missed opportunities because of the cost and because physicians refer their patients out of the office to the public clinics. Many of them never get there. We think that is another cause of missed opportunities is that physicians do not feel that they can afford to give the vaccine in their offices if they have to pay for it.

So I think there are several components of the missed opportunity.

Forgive me. Would you ask you last question again?

Mr. GANSKE. Would you be in favor of tying receipt of welfare benefits to compliance with immunization? You know, we need to have an immunized population, cost effective——

Mr. SATCHER. Let me say——

Mr. GANSKE. [continuing] decrease in disease, which is part of the reason why I am not that concerned about turning this over to the States. Clearly this is one of the few things in medicine, that

practically everybody can agree is something that we want to spend money on. There is just no question about the cost effectiveness.

That is why I feel very comfortable that State officials would make the same decision that you or I would make in terms of putting this very high on a priority list for things to use the block grant money for.

But you made a statement before that I fundamentally disagree with. You said the overall responsibility for immunization is the Federal Government's.

I think the overall responsibility for immunization lies with the parents.

Mr. SATCHER. I think what I said was if there is any responsibility that the Federal Government has it is to protect the population from diseases.

That doesn't mean that a way of doing that is not by working and educating parents and providing incentives of the kind that you are implying.

Mr. GANSKE. And that is part of your program.

Mr. SATCHER. But I am talking about the oversight.

Mr. GANSKE. Yes.

Mr. SATCHER. We support programs in this country, by the way, through our 317 program. We support programs where they use the kind of incentives that you are describing.

We don't believe it is appropriate for the Federal Government to introduce those; we've allowed local and State governments to decide what incentives they use in the 317 programs to get people immunized.

We do, in fact, provide support for State and local governments that do the kinds of things that you are implying. Chicago is one of them.

Mr. GANSKE. Speaking personally then, you have no problems with the States setting up those kind of——

Mr. SATCHER. No. States and local governments decide that they are going to use various strategies to get people immunized. I think those ought to be local constituents, and we have seen some of them work.

Mr. GANSKE. Thank you.

Mr. KLUG. Mr. Bryant?

Mr. BRYANT. Dr. Satcher, I will just ask one question because I've been unable to be here until now, but with regard to block grants I'm not interested in all this philosophical mumbo jumbo about States' rights and so forth when we are talking about kids and whether or not they are going to be vaccinated.

Is there some cost savings that can be achieved by having States do this, giving them a block grant, rather than how we are doing it now?

Mr. SATCHER. Let me confess that is not an area of our expertise. Let me say we believe that one of strengths of this program is the bulk purchase by the Federal Government, and the fact that we in fact are able to provide opportunities for States to purchase the vaccines at much lower costs than if each State had to individually purchase the vaccine.

So we believe one of the strengths of the program—one of the strengths; there are several—is in fact the whole bulk purchase

and the Federal negotiation. What we do in the Federal Government all the time, whether it is buying airline tickets for Federal workers or what have you, we negotiate on a bulk basis and we are able to provide the vaccine more cheaply.

Also, we are able to take advantage of the Federal oversight. I don't think the kind of expertise that you have at CDC in Immunizations you could ever afford to recreate in every State. There are 50 States.

We don't believe we can expect States to do that. States don't want to do that.

Mr. BRYANT. So they would have to recreate here at the State level and in effect duplicate the bureaucratic services being performed at the Federal level now?

Mr. SATCHER. In many ways they would have to duplicate expertise that is at the Federal level in order to carry out this program successfully.

Mr. BRYANT. That is the cost question. Second, from the standpoint of the children getting the vaccination, is there some evidence somewhere, in all the literature and the studies that have been done, that the kids would get these vaccinations in a more efficient way, or more kids would get vaccinations if we abandoned this program and gave it to the States in block grants?

Mr. SATCHER. There is no such evidence.

Mr. BRYANT. So what we are getting down to talking about are somebody's ideological views about Federal versus States' rights, isn't that right?

Mr. SATCHER. Again, that is not an area that I want to get into. I don't think there is any evidence in terms of what would happen if it went to State.

For me it is not a political issue. The issue is how can we best assure that we have the expertise in the Nation that we need to immunize children, and that we don't have to duplicate that in all 50 States.

Also, that we have a mechanism for providing something as critical as vaccines, which I consider to be a very good investment, by the way, at the most reasonable cost so that parents can afford it.

Mr. BRYANT. Thank you. I have no more questions.

Mr. KLUG. Thank you.

Dr. Coburn?

Mr. COBURN. Thank you. Thank you, Dr. Satcher, for being here. As I ask these questions, it is important that you understand and I understand both you and I seek the same goal.

Is it not a fact that prior to the VFC program there were two ways for children the get immunized who did not have the dollars available to get immunized, and is it not also a fact that there have not been, or at least the studies aren't there or you all don't know, that there has in fact, with this tremendous increase in expenditures, an increase in the number of children that have been immunized?

Mr. SATCHER. Let me say two things. I don't really think there has been a tremendous increase in expenditures for the VFC program. We project that in 1996, when the program is fully implemented, there will be approximately a 12 percent increase.

After having implemented this VFC program with all of the changes that that implies in terms of removing cost as a barrier—and if I forget some of your other questions, you have to help me, but you said there were two ways for children who could not afford vaccines to get them. That there were at least two ways. One was the public health clinics and the other one, I guess, you're talking about Medicaid.

Mr. COBURN. Yes, sir.

Mr. SATCHER. We've talked about that and we've talked about why we feel—I think this is probably the fundamental issue here and the issue that I think GAO—with all the respect I have for GAO—I think the fundamental issue that GAO is missing here is that it is important for parents who have family physicians or pediatricians to be able to get this important primary care services in those offices and not be referred to public health clinics.

I think that is the fundamental point that is being missed here.

Mr. COBURN. But do you have statistics or studies that show that is the reason we haven't achieved greater than 90 percent? Do you have a study that says that is the reason?

Mr. SATCHER. Let me tell you the studies that we have and you can decide whether——

Mr. COBURN. Let me make one other point. My red light is already on, and I don't know if that is appropriate or not.

In fact, you all have several studies related to this that you have not published. And is it not true that you've only published one out of five that have data relative to vaccines and what you have been doing?

Mr. SATCHER. Let's talk about studies. There are some studies that CDC has done. Let me just mention a few of them. The American Academy of Pediatrics has done a study in which they asked their members, the pediatricians in this country—and you will hear from some of them later—is it a problem for them that patients cannot afford to pay for the vaccine. The answer has been yes.

Fifty-five percent of them said that they in fact referred patients away from their offices to public health clinics, and, in fact many of them never get to the public health clinics.

For many parents it is an ordeal just to get to the doctor, let alone have to——

Mr. COBURN. Remember, I'm a family practitioner, and I have that same problem, but that is really not where I want to go with my time.

What I want to know is what have we seen early in this program in terms of the effectiveness of this program in immunizing children that otherwise weren't getting immunized before? That is what I want to know.

Mr. SATCHER. Dr. Coburn, I think I know a little bit about evaluation and surveys. That is what I did as a clinical scholar at UCLA.

I don't know of any program where you can evaluate the outcome of a program after 8 months of implementation. I don't know how anybody can do that with a national program, so I am having trouble understanding the process by which, as you are still getting more States involved—we now have 40 States which are delivering

vaccines to private physicians. All States are delivering the vaccines to public clinics.

I don't see how in the world at this point in time we could answer the question that you are asking.

Mr. KLUG. Dr. Coburn, I do not want to interrupt, but your time has expired. I would like to give Mr. Franks an opportunity.

Mr. FRANKS. Thank you very much, Mr. Chairman. I will be very brief since we do have a vote going on.

I would like to follow up on an earlier question. Could you give us any idea as to what kind of incentives and/or penalties that you would see as being appropriate to help ensure that children are being vaccinated?

I know you tried to avoid this question, but I think it is a very, very critical one, because we've seen a number of pieces of legislation that have been put forth by Democrats and Republicans on this issue tying not just benefits, but for the most part benefits, to a person having their children vaccinated.

Mr. SATCHER. We've seen different examples of incentives and penalties.

Mr. FRANKS. I would like you to tell me those examples and give me your——

Mr. SATCHER. I believe Congressman Ganske asked about the WIC program. He talked about Welfare, especially the WIC program and access to that program, being dependent upon parents demonstrating that their child has been immunized.

I think it has been shown that program——

Mr. FRANKS. That is something you would favor?

Mr. SATCHER. We support States and local governments. As long as the community was comfortable with it as a program, as I said, we would support it. That is why we try to leave those kinds of strategies to the local and State levels.

If you are talking about penalties, obviously No. 1 that jumps out at you is the one that says if your child has not been immunized in some areas by the time they are ready to go to school they can't go to school.

So that penalty is an effective one for the one thing, for saying if the State requires these four vaccines to get into school, and if your child doesn't have them, you can't go to school. The penalty have been effective.

Mr. FRANKS. And will it also show that managed care providers have done a better job at this than others?

Mr. SATCHER. CDC is working very closely with managed care providers. We have invested several million dollars in looking at the role of managed care providers in prevention.

I've detailed a full-time person in my office just to look at the relationship with managed care providers and how that relationship can expedite prevention.

It is still early to answer that question. One reason, a lot of the managed care programs do not have the full spectrum of children enrolled in terms different economic areas, but I think we will be able to answer that question later on. It is too early now.

Mr. FRANKS. Will you define it for-profit managed care and not-for-profit managed care?

Mr. SATCHER. We can.

Mr. FRANKS. Do you see that as being relevant?

Mr. SATCHER. I think it is a relevant question. I think we will be able to do that in time because we are investing in those kinds of studies.

Mr. KLUG. Dr. Satcher, we have a vote. We will give you some time to stretch while we go vote. Both myself and Dr. Coburn and several other members still have a few more questions for you. If you would please stay, and we will recess and try to get going again at 1:55.

[Brief recess.]

Mr. KLUG. We are going to resume. Dr. Satcher, again I would like to thank you for staying around because we have members with more questions, and Congressman Wyden is going to try to get back here if he can.

One of the things I want to follow up on is the GAO report, an estimation by the General Accounting Office that 10 percent of the cost of the program at this point actually went to administrative overhead. Do you agree with that conclusion?

Mr. SATCHER. The figures that were used I believe were $365 million for vaccine and $37 million for administration.

From our figures—and we need to be able to talk to GAO about that—we have different figures in terms of what has been actually expended for vaccines and what has been expended for administration.

Let me say it is very early in the program, so I must admit that we don't feel we've had enough time to look at what the administrative costs ultimately are going to be.

We think that they are moving in the right direction, but we think we can make progress in that whole issue of management and accountability.

Mr. KLUG. Congressman Wyden's point, based on the Wall Street Journal, is that there is now a review going on generally of the CDC into the cost of administration and overhead. Is that accurate?

Mr. SATCHER. Yes, that is accurate. You are putting me in the position, I think, or Congressman Wyden was putting me in a position of defending myself. I don't like to do that. I think my administrative abilities are pretty well known and proven.

The problem at CDC is a problem that took place in 1992 and 1993. We have, probably more than any Federal agency I would say, CDC has probably done a better job of streamlining; a 15 percent reduction in the employees over the last 2 years from 7,500 to 6,500. We have been more creative in terms of reorganizing programs at CDC.

So I think Congressman Wyden misinterpreted the Wall Street Journal article. The head of the Office of Personnel Management, Ron Brooks, said very clearly these problems were created in the past; CDC is making great progress in solving them.

That puts me in a position of defending myself. I know that is not my purpose for being here.

Mr. KLUG. I understand. We are now going to pass around to the members of the committee documents prepared by the administration which document the number of CDC employees who attended the Annual Immunization Conference which was held at the Cen-

tury Plaza Hotel in Beverly Hills, California; 238 CDC employees attended this conference last month for a total of just over $1 million.

Anything wrong with Atlanta as a location for a meeting and perhaps a little less ostentatious quarters?

Mr. SATCHER. Let me say two things. One, why the conference was held in Los Angeles. It was held in Los Angeles because we felt—No. 1, in terms of facilities, we wanted to attract a lot of people who were working at the grassroots level with immunization to work through problems, to solve problems together. It is an outcome of our outreach program. I think people have done an excellent job of getting people throughout the country involved in this effort, regarding some of the problems that you mentioned like parents and provider communication.

So we needed a large facility because we expected almost 2000 people. Los Angeles provided that facility, they gave us the lowest cost, they gave us the Government rate; I believe $89 for this facility. This, by the way, is the same facility where the National Education Association held its meeting 2 months ago. They asked me to come and talk about violence, which is why I know.

This was not a resort. It was not a beachfront hotel. It was a hotel that could handle a large number of people, but we also chose Los Angeles for another reason.

Historically, Los Angeles and Southern California have been plagued with high levels of morbidity and mortality from vaccine preventable diseases.

As you know, during the 1989–91 resurgence of measles, the preschool outbreak in Los Angeles was the largest in the post vaccine era. We wanted to attract a large number of people from Los Angeles and Southern California. It turned out that we attracted almost five times more people from that area that we had the year before when we had it in Charlotte.

There were two things happening here. We expected more people because of the outreach program. Also, we wanted to have it in Los Angeles, we wanted to attract people from that area where we have the greatest problem in this regard.

Let me go further and say to you, because I don't want to be dishonest, I believe we have to look at that. I believe we have to look at the way we do conferences and whether or not—especially in the age of distance learning—I don't think we can be satisfied to bring almost 2,000 people together and to pay, as you say, $1 million.

Even if we think investment in terms of the role that CDC people played at that conference and the workshops and things like that, and the participation was a good investment, but I'm interested in finding better ways to do it, and I believe we can.

Mr. KLUG. Did the money that paid for that trip come out of funds which are normally used to purchase vaccines for kids?

Mr. SATCHER. No, it came from the 317 program which is set up to do things like I mentioned to you earlier in terms of helping to strengthen State programs. That is why so many people came.

Mr. KLUG. You said specially earlier today that was one of the programs you were pointing to with pride in helping to immunize kids.

Mr. SATCHER. Yes.

Mr. KLUG. If we've got a problem in this country with children who come primarily from poor areas getting vaccinated, that is money you took out of their vaccination program, and I don't think you find a lot of those kind of kids in Beverly Hills.

Mr. SATCHER. We found a lot of people from throughout the country who worked with those kids who attended that meeting because they had been involved with outreach programs to strengthen at the local and State level.

We can talk a lot about Beverly Hills, but this particular hotel is known for its expertise in running large conferences, and we paid a rate there that we would probably pay in Madison, Wisconsin in order to have this conference.

We would not have been there if we could not have gotten that rate. It is not a resort area, it is not on a beachfront. There is not a lot else to do when you attend a conference at Century Plaza.

Mr. KLUG. And let me get this right. This is some seat of the pants arithmetic, but at $1 million, our costs show that could vaccinate approximately 13,500 children. Do you think that is a better way to spend the money?

Mr. SATCHER. It depends how many children get vaccinated because of the conference, and I think the people who came to that conference are people who are committed to helping children get vaccinated by working with parents, working with school systems, working with nurses, working with physician assistants and providers to try to get the kind of things you talked about earlier in terms of what are some of the real barriers other than costs. And they are motivating parents, educating parents, mobilizing communities around immunization programs.

So I would have to compare the outcome in terms of the people who have made the commitment. Many of them are volunteers, by the way, who are willing to walk the streets.

I remember going with some of them to tenement houses in Harlem. They would go in and sit down with parents, go over immunization schedules and talk about why it was so important.

Many of these people are committed. They volunteer, and they attended.

But having said all that, I believe that there is probably a better way we can do it, and we will look for it.

Mr. KLUG. The Wall Street Journal article indicates that you have a number of workers on your staff that have no direct connection to the Agency's primary mission.

You have a travel agency inhouse?

Mr. SATCHER. There is SATO. I'm sorry I don't know all of the details of that, but when the Government contracts for travel for its employees, there is a travel agency that is selected, and then there is an airline every year that is selected as a primary airline.

I believe the SATO offices are in fact a part of CDC.

Mr. KLUG. As somebody who is very interested in privatization, if the Wall Street Journal article is accurate, and you have folks on your payroll who specialize in doing travel and architects——

Mr. SATCHER. We have a lot of people who travel at CDC, not only within the country——

Mr. KLUG. Obviously to the conference.

Mr. SATCHER. But also to Zaire to stop an epidemic before it gets to this country. Travel is a very important part of what CDC does.

Mr. KLUG. Doctor, obviously I am not going to be in a position where I'm going to tell you you shouldn't send people to Africa to track the Ebola outbreak and possible implications not only for health in Africa, but the States, but in my mind, when we've been fighting all morning about the most effective way to spend money on children's vaccination programs, I guess I would rather see the million dollars go to the vaccination program.

Mr. SATCHER. I am not going to disagree with you because I am not going to say that we could not have done a better job with that.

Before I have a chance to look at all the details of it, because if you were to ask me today if I thought that I could improve upon that, I believe so, and I am going to find a way to do it.

Mr. KLUG. Let me also indicate for the record and then I will turn to my colleagues, this is a letter we have actually pending with the Agency for a number of financial records we've requested, including some of the numbers that were outstanding that GAO made reference to earlier today.

You've done a very good job testifying with us today, and it is my hope that we will get a response to the rest of the questions.

[The letter referred to follows:]

U.S. HOUSE OF REPRESENTATIVES,
COMMITTEE ON COMMERCE,
Washington, DC, June 12, 1995.

DR. WALTER ORENSTEIN
Director, National Immunization Program, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E.
Atlanta, GA.

DEAR DR. ORENSTEIN: This letter concerns the Commerce Committee's interest in the total amount of expenditures associated with VFC-related operations (whether direct or indirect and whether provided under VFC, 317, discretionary, travel, or other HHS appropriations). We would like you to provide us with information on: (1) VFC program-related expenditures for FY '94 and '95; and (2) the federal and states' expenditures associated with the 29th National Immunization Conference held in Los Angeles from May 15–19, 1995

VFC PROGRAM RELATED EXPENDITURES

On April 4, 1995, your staff provided each immunization project's FY95 budgetary allotment for VFC distribution, operations, ordering, and vaccine. In order to understand how VFC funds have been expended so far, we would also like you to identify any other HHS costs or expenditures associated with implementing or operating VFC that have been incurred outside these projects' budgets for FY '94 and '95.

"Other HHS costs or expenditures associated with VFC" would include costs of HHS staff time associated with VFC operation, implementation, legal matters or contract negotiation, whether incurred by CDC, HCFA, PHS, or other HHS units. We are also requesting HHS expenditures or obligations associated with any VFC-related travel, training, contracts, equipment or interagency agreements and the amounts of any disbursements to states or immunization projects, other than those covered in the VFC project accounts mentioned above, that are wholly or partially attributable to VFC.

Specific examples of such expenditures would include expenses for any meetings held wholly or partially for the purpose of planning, implementing, or operating VFC, such as the VACMAN computer software uses' conference, meetings with immunization project officials, and relevant portions of the 28th and 29th National Immunization Conference. Your reply should also include the costs of associated contracts with Batelle, the Logistics Management Institute, the Center for Health Policy Studies, Mercer Management Consulting, and the development of any computer system to develop state wide immunization registries, among others. To the extent that such expenditures are only partially attributable to VFC, please estimate the portion of expenditures or activities directed to VFC.

In addition, please supply the total FY95 operating budget for NIP, and each of the programs it administers (e.g., 317, VFC), so that we may separately estimate NIP's VFC-related overhead as a percentage of the NIP operating budget. Also, please specify the total amount of funds spent on development of a distribution system under GSA. We would also like to know the total amount of federal funds allocated to each state and the amount spent so far on distributing VFC vaccines by each state.

FEDERAL EXPENSES RELATED TO THE 29TH NATIONAL IMMUNIZATION CONFERENCE

With respect to the 29th National Immunization Conference recently held in Los Angeles, we would like information on the number and level of CDC staff in attendance, their transportation costs, length of attendance, and per diem expenses as contrasted to the same information for the 28th National Immunization Conference. In addition, please provide information on all federal costs associated with the meeting—to include rental of hotel meeting rooms, transportation provided for meeting attendees, registration services, travel grants to non-federal attendees, speakers' fees, catering, etc.—as contrasted to similar expenses for the previous year's meeting. To the extent possible, please also identify the amounts and sources of funds state immunization personnel used to attend the meeting (i.e., IAP grants, VFC operations, other federal funds, or non-federal funds).

In addition, we would like you to provide us total expenditures associated with Random Digit Dialing, as well as the National Health Interview Survey for monitoring immunization rates, and the source of their funding.

We would like your response to this request by Tuesday, June 13, 1995.

Sincerely,

THOMAS J. BLILEY, JR.,
Chairman, Committee on Commerce.

Mr. SATCHER. We plan to provide you all the information. The information that you have not received from us that you've requested, if it is available we will get it to you. I guarantee you that.

[Information not received at time of publication.]

Mr. KLUG. Thank you very much. Again, I know some of my colleagues had questions that were pending when we left. Dr. Coburn, can I go to you and then to Mr. Frank.

Mr. COBURN. Thank you.

I just have one other question for you. Does the CDC have data that shows children who are seen in the doctor's office who are then referred to a 317 clinic, funded clinic, and do, in fact, not get significant quantities of immunizations as recommended by the physicians? Do you have a study that shows that?

And do you have a study that shows that has now improved?

Mr. SATCHER. I think what has happened with the VFC program, I think it is much too early to evaluate the outcome of it, especially since it is not fully implemented.

But let me say that we do have studies that we think show that, and let me just give you one example because you might debate that.

We have studies showing that for an uninsured child who may be sent from a physician, and you track them and see if they get the vaccine and when they get it. I think we have studies showing both, that the time in which a child that is insured and gets a vaccine is anywhere from 4 to 6 months earlier than a child that is uninsured.

Mr. COBURN. That is different than the question that I asked you.

Mr. SATCHER. We are talking about fully vaccinated by the age of two.

Mr. COBURN. What I'm trying to get to is I'm not sure that the problem that was identified that started the VFC and the program was a real problem. That is why. Even though I know I had difficulty with parents under the old system, making sure that they got vaccinated, I'm not sure that there is a study that says that there is a difference in terms of how we are trying to deliver this now versus what we were delivering them if, in fact, there was a significant difference in the number of children that were immunized who were referred to the health department.

Mr. SATCHER. I'll say two things, Dr. Coburn. No. 1, one of the things we are doing, we trust the States and we trust the providers and we trust the provider organizations. You are going to hear from some of them later and they will give you specific examples and I am confident that this program speaks to a problem in getting children immunized.

We have our studies but they probably have something better than our studies. You know, they have the experience of their members, they have their own experience running a State program like Dr. Smith, and I believe it is consistent with what we are saying.

Mr. COBURN. Okay, thank you very much.

Mr. KLUG. Mr. Bryant, do you have any questions?

Mr. BRYANT. Yes.

Dr. Satcher, I guess my question really is for the chairman of the committee. I was wondering, did the committee pay to have these pictures made and blown up?

Mr. KLUG. GAO did.

Mr. BRYANT. Did you ask them to do it?

Mr. KLUG. Yes, sir.

Mr. BRYANT. How much did it cost to have these four pictures made and blown up?

Mr. KLUG. I don't know but we will find out that information for you.

Mr. BRYANT. Please get it to us immediately. It is critically important to the future of the health care of the American people that I have that information.

Mr. SATCHER. You know, I spent 7 years working very closely with organizations like the Brotherhood Crusade. For some reason, every year, the Brotherhood Crusade had their fundraiser at that same hotel because they got good rates and they got a lot of support.

Mr. BRYANT. I hesitate to dignify what I view as an outrageous attempt to draw the public's attention away from what your Agency does by spending money on these things but I guess I would like to ask you for the record, is this hotel extraordinarily expensive relative to other places where you might have had this meeting?

Mr. SATCHER. We paid $89 per night.

Mr. BRYANT. $89 a night?

Mr. SATCHER. Yes. That was the——

Mr. CORDERO. We paid what is the per diem rate. This was the only hotel that would give us the rate.

Mr. BRYANT. So regardless of these pictures and regardless of where it might have taken place, you have a certain limit on what

you can spend as a Federal agency and you didn't exceed that limit, is that correct?

Mr. SATCHER. No. They gave us the government rate for that area.

Mr. BRYANT. Very well.

Mr. SATCHER. In fact, it is a better rate than I get here in Washington when I stay at the Holiday Inn.

Mr. BRYANT. So if the chairman of this subcommittee and the staff of this subcommittee had come to you ahead of time and asked you that question, they could have saved the money they wasted making these big blowups to come in here and try to embarrass you today. That's the way it appears to me. I won't ask you to answer that question but that is pretty obvious that they could have, had they been willing to come ask you that question in advance, instead of trying to sandbag you with these pictures, they could have saved whatever money it took this subcommittee to pay for taking these pictures and probably a lot more in order to get just the right one, and then have them blown up.

I would just like to say that I think in view of the great work your Agency does and the enormous, frightening problems that you are facing, the ebola virus and everything else, that to take the time of this committee and to take the time of the American people and all the people in this room with in my view a crude diversion like this is an outrage and I am sorry that you had to sit through it.

I yield back my time.

Mr. KLUG. Thank you.

Mr. Greenwood?

Mr. GREENWOOD. I would like to participate some more in the crude diversion. Primarily because, contrary to the previous speaker, if Members of Congress don't question Federal agencies about travel and conferences, clearly no one will. And if anybody thinks that excessive moneys are not spent in this town for travel and conferences, they are out of touch.

I wasn't going to do this, but now I sort of feel compelled to a little bit. $89 a day for a room doesn't sound like a lot of money but what does sound like a lot of money, if the information staff has given me is correct, is that the CDC also paid several hundred thousand dollars to the hotel to augment the room fee; isn't that right? Wasn't there $700- or $800,000 that was paid additionally to the hotel?

Mr. SATCHER. To augment the room? I'm sorry, I am missing something.

Mr. GREENWOOD. For services for all of the conference. In other words, when you arrange a conference, you negotiate what your fee is going to be for each of the participants for their rooms and then you also negotiate a fee to pay for everything else that you get in the hotel.

Mr. SATCHER. All of those things were looked at in selecting this hotel in terms of whether they could provide the services and how it compared with other places. I was just looking at some of the places, I don't have it in front of me now, but we considered St. Louis, Denver, San Diego, Dallas, Phoenix and several others in terms of having this conference and comparing hotels.

Mr. GREENWOOD. Didn't this conference cost you three times what the conference had cost you before?

Mr. SATCHER. The year before we had 700 people. I believe at this conference we had about 1,700 and one of the major goals of the conference was in fact to get more people there who were working at the grassroots level.

Mr. GREENWOOD. Who decides how many folks from Central Office get—is there a right number of people to send to the conference? According to our notes here, 127 people from Central—from Headquarters staff were out there. Frankly, if you told me there were 127 Headquarters working on this whole program I would be astonished at that alone, to know that 127 of them were necessary to go out to a conference.

Mr. SATCHER. Let me say, my staff tells me that there were no extra charges for meeting rooms at the Century Plaza. That is getting back to an earlier point, but let me get to the other point in terms of the people who attended this conference where there were about 1,700 people in attendance who work at the grassroots levels in immunization.

At least 90 of the CDC people were presenters at the conference. I believe at least 50 of them were new employees in the immunization program because as we cut other CDC programs, we have increased the size of the immunization program. So some of them were new and we felt they needed to go to this conference and they needed to interact with people they were going to be working with.

I can justify it but, in all fairness, and I am not sure even my staff will like this——

Mr. GREENWOOD. And it's 176 people.

Mr. SATCHER. If you say to me, you need to look at this, Dr. Satcher, and see if there is a better way to do it, I would say I agree.

Mr. GREENWOOD. How many folks do you have working in this program at CDC?

Mr. SATCHER. The number of people working in the National Immunization Program is about 300?

Mr. CORDERO. A little over 300 including headquarters.

Mr. GREENWOOD. Does that include field staff?

Mr. CORDERO. Yes, sir.

Mr. GREENWOOD. That includes clerical staff?

Mr. CORDERO. Yes, sir.

Mr. GREENWOOD. So you have about 300 people and you took 238 of them to the conference?

Mr. SATCHER. A lot of the people didn't come from CDC. I want to make that clear.

Mr. GREENWOOD. No, I understand that, but——

Mr. SATCHER. They were located in Los Angeles and other parts of California.

Mr. GREENWOOD. But 176 of your Headquarters staff and 62 of your field staff, which is 238 out of 300 staff people, went to this conference. It would seem to me that if you subtracted the people who were clearly, simply support and clerical, have nothing to do with programs, it sounds like you took everybody.

Mr. SATCHER. It is the major immunization conference in the country during the year. It is the No. 1 conference.

Mr. GREENWOOD. But nobody sends everybody on their staff to the conference.

Mr. SATCHER. No, I agree, we don't.

Mr. GREENWOOD. And especially when the average stay was 6 or 7 days.

Mr. SATCHER. I don't think it's appropriate to send everybody——

Mr. GREENWOOD. You did.

Mr. SATCHER. I don't think we sent everybody. But I think——

Mr. GREENWOOD. I'll bet you you sent virtually everybody who wasn't a typist.

Mr. SATCHER. Let me say what I will say. Ninety people had presentations before these 1,700 attendees and, as I said before, there were at least 40 to 50 people who were new to the program and still learning and needed to be at this conference in terms of sharing and getting to know the people they were working with.

So I think we can "justify" this if people ask us to do it. I don't know how much time you want to spend on that. We can justify it.

But at the same time, if you said to me—if you think you've got a better way to do this, if you've got technology, you've got distance learning, I would say we continue to look for better ways to do conferences.

I mentioned that we educated about 15,000 physicians and nurses in immunization. We were able to use satellite downlinks. I don't think we could have done that with this conference but we did find a very innovative way to reach people who are busy working in their offices. So we are looking at ways to improve not just CDC. We are working with other parts of the government, we are working with academia, public health—state public health officers and finding out how we can do a better job of communicating without coming together in one city.

Mr. GREENWOOD. Thank you. By the way, the hotel just called and said they are going to cover the cost of reproduction for the free advertising.

Mr. KLUG. Let me recognize Mr. Waxman who will stand up for the workers in the hotel who live in his district.

Mr. WAXMAN. I was surprised to come in and see these blown-up photos of one of the fine hotels in my district. We take a great deal of pride in hosting a number of events. In fact, many of the members of this committee have been flown out to the district, to many of these hotels in my district, the Beverly Wilshire, the Beverly Hills, the Century Plaza Hotel, usually at the expense of some lobbying organization that invited them to come and give some speeches.

I do recommend these hotels, they're very good, and the sun usually shines in Los Angeles so it is a good place for a meeting.

Mr. KLUG. Thank you, Mr. Waxman. There will be brochures handed out at the back of the room as we leave.

Mr. GREENWOOD. Mr. Chairman?

I understand that Mr. Waxman would recommend the hotel. I wondered did he recommend the hotel.

Mr. WAXMAN. I didn't get a commission, nor did I make the recommendation.

Mr. KLUG. Dr. Satcher, you have been very patient with us today. Frankly, as our other panelists are still waiting to testify and we have a vote in front of us, we're going to break. You are obviously free to leave at this point and I am sure delighted to be. But thanks for your time and your attention and we look forward to your responses on the other questions.

We will be adjourned——

Mr. SATCHER. We will get the responses to you, including the agenda for the conference.

[Brief recess.]

Mr. BILIRAKIS. The hearing will come to order.

I know that most of you are veterans up here and know how things work and fail to work, so I guess apologies are not really that necessary, but on behalf of the committee, I do apologize, but that's the way it goes. These votes take place and we've got to be there.

Our third panel consists of individuals who will testify regarding the impact of the VFC program on the research and development of new vaccine products for children, certainly a very significant point.

The first witness will be Mr. Lance Hackett, vice president of Mercer Management Consulting, who is accompanied by Jeff Totten.

Mercer was originally hired by HHS to conduct a study on this very issue, and during the course of the study the scope was changed by HHS as I understand it. Mercer will present what they believe the results of their study would have been, had they been permitted to complete it.

The second witness is Mr. Henry Grabowski, an economist from Duke University, I guess, I don't see him here. Is he here, is he on his way? In case he shows, he is an economist from Duke University who has expertise in the economics of the pharmaceutical industry.

The next two witnesses are chairmen of small biotechnology companies that are interested in pursuing products for children. The first is Leighton Read of Aviron and the next is Lance Gordon of OraVax. Both gentleman will describe the difficulty in acquiring venture capital funds.

Our final witness will be Mr. Gordon Douglas of Merck. Mr. Douglas is a member of the National Vaccine Advisory Committee and will testify about the NVAC meeting on May 11, 1995, where the Mercer Study for HHS was discussed.

Certainly all of your written testimonies are part of the record, and I would like to have all of you limit your testimony to 5 minutes if you possibly can. Hopefully in the process of the questioning most of your points can be gotten across. All right, we will start off with Mr. Hackett.

STATEMENTS OF LANCE B. HACKETT, VICE PRESIDENT, MERCER MANAGEMENT CONSULTING; HENRY GRABOWSKI, ON BEHALF OF DUKE UNIVERSITY; J. LEIGHTON READ, ON BEHALF OF AVIRON, INC.; LANCE K. GORDON, ON BEHALF OF ORAVAX; AND R. GORDON DOUGLAS, JR., MERCK VACCINE DIVISION, MERCK & COMPANY

Mr. HACKETT. Thank you.

Mercer Management Consulting was contracted in September 1994 to conduct a study of the U.S. vaccine industry by the Department of Health and Human Services. The purpose of the study, and I quote from it, to develop an understanding of the economics of the U.S. vaccine industry that will enable the U.S. Government to establish vaccine procurement mechanisms and fair payment prices in order to adequately sustain private sector research and development on new and improved vaccines.

The study was specifically requested by a resolution of the National Vaccine Advisory Committee in response to the statement of managers for 1993 that states, "if the Secretary concludes that the statutory prices for current vaccines does not allow for sufficient research and development subsidies, the Secretary is expected to report this to Congress and to request a statutory amendment to the price limitation."

In January 1995, the scope of the study was modified by DHHS to focus our efforts on the economics of production, distribution, sales and marketing. The modified scope excluded further analysis of the suppliers' investments in R&D and the impact of the VFC program legislation on the industry's economics, in particular on revenue costs in R&D investments.

We were told that without the R&D spending data from suppliers and reliable estimates of the volume of government purchases under VFC, the analysis of these effects was too speculative. The modified scope also excluded the creation of policy options for managing the Federal purchase of vaccines.

At the time the scope of the study was modified, we had completed a preliminary review of the VFC effects of R&D and were working with CDC to further refine and satisfy their concerns. With the modification of scope, we halted any further analysis of the topic. Nonetheless, we believe we can make the following remarks:

The key element of VFC impacting the procurement of vaccines and thus industry economics is the expansion of the childhood population eligible for free vaccines bought at Federal contract prices. From primarily uninsured today to include the under-insured, native Americans and Medicaid recipients and, at the discretion of individual States, potentially all the children within a State.

Because prices paid for vaccines sold on government contract are discounted from between 35 percent to over 80 percent of the list price in the private market, shifting volume to the public market at the lower prices will have significant negative impact on cash-flow. VFC's capping prices of these products negate the opportunity for suppliers to raise price to recapture lost cash-flow.

Additionally, shifting the private market volume to the Federal contract creates a near-monopoly purchaser and considerable uncertainty over the profitability of future vaccines. Increasing the

uncertainty of future profits is expected to have a negative impact on the supplier's investment in R&D.

We have prepared an exhibit that is in the written statement to demonstrate our points here.

The determination of the impact of VFC n R&D and the resulting costs to our society requires a four-step analysis as illustrated below or over here. The first step is to understand the cash-flow effect on the industry from increased public purchases at capped prices. Our analysis, although it was preliminary and stopped before we were completing it, would indicate that the lost cash-flow is in the range of about $100 million.

The major unknown is how much incremental vaccine purchases will be made at the public price once VFC is fully implemented. CDC's initial estimate is that the government purchases 78 percent of the doses distributed, a 28 percent increase over pre-VFC levels. Assuming the 78 percent rate, VFC would generate a reduction in cash-flow of between $90 to $120 million.

CDC believes that VFC legislation provides a benefit to suppliers that possibly offsets the cashflow loss. Under VFC the government is required to purchase, as an entitlement, new vaccines if they are placed on the childhood schedule by the ACIP. The ACIP is empowered to act with independent authority in evaluating the health merits of new vaccines without consideration of the budgetary effects of funding the purchase.

If a new vaccine is accepted on the schedule, the sales of the vaccine supplier during the first few years of introduction would likely be higher than pre-VFC. Because the funding is automatic, it applies to a large quantity of doses although at a lower public market price.

Mr. BILIRAKIS. Mr. Hackett?

Mr. HACKETT. Yes.

Mr. BILIRAKIS. The time is up. Forgive me but if you could sort of summarize, if you could, then hopefully, again, a lot of the points can be made during the questioning.

Mr. HACKETT. Let me sum up by pointing to the chart.

In trying to follow through the impact of VFC on our Nation's economy and our society, it goes through this four-step process. The top number we said is $100 million. The impact on the supplier's R&D is a more difficult number to estimate because it involves the individual decisions of the individual companies. But if we look at historical norms and what they have done historically with R&D, one would estimate that about $30 to $40 million would be extracted from R&D which means that we would hamper the development of new products which, given the testimony earlier today that those new products carry a very large impact on reducing health care costs because of the impact of vaccination versus the cost of cure. The overall impact on the economy would be quite large.

We were unable to complete that analysis when we finished.

[The prepared statement of Lance Hackett follows:]

PREPARED STATEMENT OF LANCE HACKETT, VICE PRESIDENT, MERCER MANAGEMENT CONSULTING

Mercer Management Consulting was contracted in September 1994 to conduct a study of the United States vaccine industry for the Department of Health and Human Services (DHHS). The purpose of this study was:

To develop an understanding of the economics of the U.S. vaccine industry that will enable the U.S. Government to establish vaccine procurement mechanisms and fair payment prices in order to adequately sustain private sector research and development on new and improved vaccines.

The study was specifically requested by resolution of the National Vaccine Advisory Committee in response to the Statement of Managers for OBRA '93 that states: "if the Secretary concludes that the statutory prices for current vaccines does not allow for sufficient research and development subsidies, the Secretary is expected to report this to the Congress and to request a statutory amendment to the price limitation."

In January 1995 the scope of the study was modified by DHHS to focus our efforts on the economics of vaccine production, distribution, and sales and marketing. The modified scope excluded further analysis of the suppliers' investments in research and development, and the impact of Vaccines for Children (OBRA '93) legislation on vaccine industry economics (i.e. revenues, costs and R&D investments.) We were told that without R&D spending data from suppliers and reliable estimates of the volume of government purchases under VFC the analysis of these effects was too speculative. The modified scope also excluded the creation of policy options for managing the Federal purchases of vaccines.

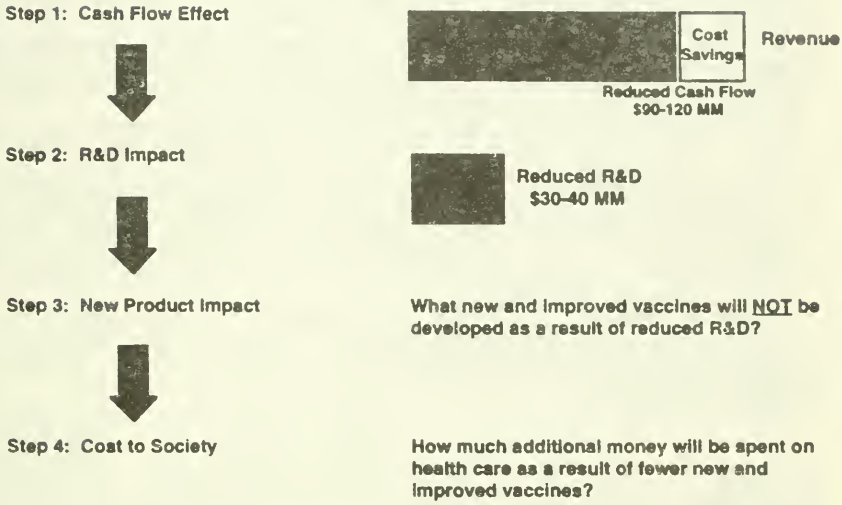
At the time the scope of the study was modified, we had completed a preliminary review of the VFC effects on R&D and were working with CDC to further refine the analysis to satisfy their concerns. With the modification of scope, we halted any further analysis of this topic. Nonetheless, we can make the following remarks.

The key element of VFC impacting the procurement of vaccines, and thus industry economics, is the expansion of the childhood population eligible for free vaccines bought at Federal contract prices—from primarily the uninsured today to include the "underinsured", Native Americans, Medicaid recipients, and, at the discretion of individual states, potentially *all children* within a state. Because prices paid for vaccines sold on government contract are discounted from between 35 percent to over 80 percent of list price in the private market, shifting volume to the public market at those lower prices will have a significant negative impact on cash flow. VFC's capping prices of these products negates the opportunity for suppliers to raise prices to recapture lost cash flow.

Additionally, shifting private market volume to the Federal contract creates a near monopsony purchaser, and considerable uncertainty over the profitability of future vaccines. Increasing the uncertainty of future profits is expected to have a negative impact on the supplier's investment in R&D.

The determination of the impact of VFC on R&D and the resulting cost to our society requires a four step analysis as illustrated in the exhibit below:

Preliminary Estimates of VFC Effects
– Reflecting Increased Government Purchases –



The *first step* is to determine the effect on industry cash flows from increased public purchases at capped prices. To estimate this, the volume shifted from the private market to the Federal contract is multiplied by the difference between the two prices and then adjusted for the lower selling, marketing, and distribution costs required to serve the public market (referred to as "cost savings" in the exhibit.) The major unknown is how much incremental vaccine purchases will be made at the public price once VFC is fully implemented. CDC's initial estimate was that the government would purchase 78 percent of doses distributed, a 28 percent increase over pre-VFC levels. Assuming the 78 percent rate, VFC would generate a reduction in cash flow of approximately $90-120 million per year.

CDC believes that VFC legislation provides a benefit to the suppliers that partially offsets the cash flow loss. Under VFC, the government is required to purchase, as an entitlement, new vaccines if they are placed on the Childhood Schedule by the ACIP. The ACIP is empowered to act with independent authority in evaluating the health merits of new vaccines, without consideration of the budgetary effects of funding the purchase. If a new vaccine is accepted on the schedule, the sales of the vaccine supplier during the first few years of introduction would likely be higher than pre-VFC, because the funding is automatic and applies to larger quantity of doses—although at the lower public market price.

The vaccine suppliers, however, believe that this element of VFC will not have a material effect on their economics; that the short term benefit of higher sales volume is more than offset by the longer term cost of larger public purchases of the new vaccines at lower prices.

We had not yet estimated this potentially offsetting effect when the scope of the study was modified.

The *second step* of the analysis is to determine the likely reduction in R&D as a result of the reduction in cash flow. This is a more difficult question because the answer requires a projection of how the pharmaceutical companies will react to the loss of cash flow. The answer is probably situational. Individual suppliers will react differently depending on many factors, but in particular on the scientific and commercial promise of products that are in the R&D pipeline, and the degree that VFC impacts their company. The VFC impact varies significantly by supplier.

We can, however, make a number of observations:

1. The $90-120 million loss in cash flows will need to be absorbed by a reduction in profits or R&D investments.

2. Vaccine businesses are independent profit centers within their parent pharmaceutical companies, and are expected over time to generate financial returns similar

to pharmaceutical averages. It is unlikely that the parent will allow its vaccine business to reduce profits to the full extent of the cash flow reduction.

3. Historically, pharmaceutical firms have tended to reinvest between 30 and 40 percent of cash flow contribution (defined as pretax, pre-interest profit plus R&D expenses) in R&D spending.

Thus, we believe there will likely be a significant reduction in U.S. vaccine R&D as VFC policy is implemented. A preliminary estimate would be $30-40 million per year.

The *third and fourth steps* have not been analyzed by us. We believe there is a strong case to be made, however, that the overall cost to our society in increased health care expenditures due to fewer new and improved vaccines considerably exceeds the benefits of lower costs of vaccine procurement.

To understand more fully the potential impact of VFC on industry R&D investments, we need to look beyond the near term cash flow implications—cash flow analysis alone is inconclusive.

For example, if reducing industry cash flow has a negative impact on R&D then if we pay higher prices for vaccines will it not increase R&D investments? If so, where do you stop? Why not double or triple the price of vaccines to fund much larger R&D budgets? If money spent on R&D in vaccines has historically been paid back many times over in tangible reductions to our nation's health care cost, where is the point of diminishing returns?

Also, if the government acts on the conclusions in our vaccine study (the report was delivered to the DHHS yesterday), then competition in the U.S. market will intensify and vaccine cash flow will, likely fall as a result. So how can we argue for increased competition and still believe that the negative cash flow impact of VFC will hurt the industry?

The real problem with VFC is that it casts a black cloud over the industry—it establishes the Federal government as the driver of the vaccine business. It introduces the idea of price controls and broadens the role and power of the government as a near monopsony purchaser. As one biotech company put it, "It is dangerous to get in bed with an elephant, it might roll over!" It is one thing for the suppliers to lose cash flow to competition. That will force them to become more efficient and more effective, or get out of the business if they can no longer compete. It is totally different to lose cash flow to government action.

This industry operates on the premise that most R&D is spent on unproductive investigations, but with enough effort, a blockbuster vaccine will be found which will justify all the money spent on R&D. Hep B is a good example. When the government caps the upside on successful vaccines, (by increasing its purchasing power and introducing price controls) it discourages investment in R&D. Venture capitalists can quickly move their funds to other areas, perhaps outside of health care, pharmaceutical managers can look for R&D investments in other markets and biotechs can shift vaccine research to adult applications. It is quite conceivable that the loss in R&D investment due to the psychological effect will be much larger than $30-40 million.

One venture capitalist we spoke with put it succinctly. He said "the problem with VFC is that it is an example of government regulation to correct the problems caused by government regulation." The U.S. pays the highest prices in the world for vaccines and government intervention is a major cause. The government hinders exports, which reduces the relative size and efficiency of U.S. production, and further raises development and production costs through lengthy PLA and ELA processes. Moreover, regulation has restricted competition to the point that we have a monopoly supplier for OPV, a product which is over 30 years old and supplied to the rest of the world at a fraction of the price we pay in the private market.

The vaccine industry went through a period several years ago when it developed very few new vaccines. It is currently going through a period of significant development, largely due to the high prices paid in the U.S., and as a result, a number of valuable new vaccines have been introduced in recent years or are in the pipeline.

VFC threatens to undermine childhood vaccine R&D through the loss of near term cash flow and the creation of the government as a near monopsony purchaser—casting a black cloud on the industry. What is needed, instead, is a government/industry partnership which addresses the shared interests of a steady supply of new and improved vaccines, high levels of immunization and stable production, and the need to lighten the regulatory burden to create a more efficient and competitive industry. It will be very difficult to create a partnership while VFC remains in its current form.

Mr. BILIRAKIS. Thank you, sir.

Mr. Grabowski. Welcome.

STATEMENT OF HENRY G. GRABOWSKI

Mr. GRABOWSKI. Thank you, Mr. Chairman.

The key point in my statement is that the replacement of the private market for children's vaccines by the government under the VFC program will have very adverse effects on vaccine innovation. While today's vaccines will be cheaper, the development of tomorrow's vaccines will be slower. A slowdown in vaccine innovation will in turn have unfavorable long-term effects on health care and health care expenditures. This is because new vaccines embody a disease preventative approach and they have traditionally exhibited large benefit to cost ratios.

Over the past decade, the search for new vaccines has enjoyed a particular renaissance with the emergence of biotechnology. Hence, this is a particularly critical period for vaccine development and one in which I believe the VFC program could do damage to R&D incentives.

My statement makes several points about the R&D investment process for pharmaceuticals and vaccines that are relevant to assessing the effects of government controls on innovation and I might add that I am an economist that has been studying the R&D investment process in this and related industries for over two decades now.

The first point I would like to make is that there is mounting evidence that the R&D process is becoming longer and costlier. In a study by the Center for the Study of Drug Development at Tufts that I participated in, my colleagues and I estimated that it takes 12 years and over $231 million—that's in 1987 dollars—to develop and discover a new drug. While our work is focused on pharmaceuticals, we have reason to believe that R&D cost and times for new vaccines are comparable to those for pharmaceuticals. In addition, however, FDA regulation requires that the manufacturing process for a new vaccine be scaled up and validated much earlier in the R&D cycle than for a new drug and this adds tens of millions of dollars of extra capitalized costs to the R&D process for a new vaccine.

A second major point is with regard to revenues. With respect to revenues, the potential for major new vaccines is constrained by much smaller market sizes than for major new pharmaceuticals. The reason includes the inherent nature of vaccines which are consumed only once or a few items over a lifetime, as well as many biases in our medical system for treatment therapies over prevention.

Fortunately, this situation is changing with the growth of managed care and a new sensitivity to costs and benefits of medical therapies.

A third major point that emerges from our research at Duke on the R&D investment process is that their distribution of returns is highly variable. The search for new drugs is now centered around breakthrough therapies for unmet needs that can cover both the large fixed cost of R&D and many unsuccessful compounds that are clinically investigated but never commercialized.

Now, given this economic environment, government controls under the VFC program will particularly have negative impacts on vaccine innovation. First, government monopoly purchasing at

below market prices significantly lowers the expected returns on new children's vaccine. It also reduces the cash-flows available to undertake R&D investment in children's vaccine. That is one of the major points on the chart there.

The VFC program sends the message that the children's vaccines that are tomorrow's breakthroughs will have virtually no private market. Given the great uncertainty regarding the returns on and prices for these vaccines, one can expect R&D resources to shift to other therapies. The greatest negative effect would be on long-term discovery research. This research is the riskiest and the furthest away from commercial introduction.

My statement also makes the point that increased government controls on vaccines will have especially negative consequences for smaller firms exploring new technologies and I am sure that will be taken up by others on the panel.

So in conclusion, I believe that government price regulation is a bulldozer approach to the societal problem that will have significant unintended negative effects on the incentives for R&D by biotech and pharmaceutical firms.

[The prepared statement of Henry G. Grabowski follows:]

PREPARED STATEMENT OF HENRY G. GRABOWSKI, PH.D., DUKE UNIVERSITY

Under the Vaccines for Children Program and OBRA 93, government purchases of children's vaccines will grow to over 80 percent of U.S. consumption. Ten years ago, the government accounted for only about a third of this market. The rapid displacement by government of the private market for children's vaccine sends a very chilling message to vaccine innovators.

While today's vaccines will be cheaper, the development of tomorrow's vaccines will be slower. This is unfortunate because the scientific opportunities for new vaccines have proliferated with the growth of biotechnology. One recent data source shows over 100 firms with vaccine R&D programs in 1993, focused on several major disease areas. Furthermore, vaccines, which embody a disease-preventive approach, have traditionally exhibited large benefit-to-cost ratios from a societal perspective. A slowdown in vaccine innovation will have very unfavorable consequences for both health care and health expenditures.

The R&D Investment Process

This is a time of exploding opportunities for pharmaceutical advances. New research techniques associated with biotechnology and related fields have helped enhance the search for significant new medicines. Vaccine R&D has enjoyed a particular renaissance over the past decade. There are many important vaccines in development, including safer versions of existing vaccines as well as new vaccines for diseases such as influenza, cancer, diabetes, TB, and AIDS.

Although there is great optimism about the scientific potential for important discoveries involving drugs and vaccines, there is also mounting evidence that the R&D process is becoming longer and costlier. The median development time is now twelve years from synthesis to FDA approval. In a study sponsored by the Center for the Study of Drug Development at Tufts University, my colleagues and I estimated that it takes an average of $231 million (in 1987 dollars) to discover and develop a new drug.[1] Aggregate trends on recent R&D expenditures and new drug investigations indicate that current costs are much higher.

Our research on R&D costs has been focused more on new chemical compounds than biologicals, given the preponderance of the former in R&D spending and introductions. Nevertheless, we have reason to believe that R&D costs and times for new vaccines are comparable to those for pharmaceuticals. In addition, however, FDA regulation requires that the manufacturing process for a new vaccine be scaled up and validated much earlier in the R&D cycle than for a new drug. This adds tens

[1] DiMasi, J., Hansen, R., Grabowski, H., and Lasagna, L. "The cost of Innovation in the Pharmaceutical Industry," *Journal of Health Economics*, Volume 10; 1991; pp. 107-142.

of millions of dollars of extra capitalized costs to the R&D process for a new vaccine.[2]

While this is the case, the revenue potential for major new vaccines is constrained by much smaller market sizes than for major new pharmaceuticals. One reason this is inherent in the nature of vaccines which are consumed only once or a few times over a lifetime. This is compared to a new pharmaceutical which may involve treatment of a chronic condition over many years. It also reflects many biases in our medical system for treatment therapies over prevention. Fortunately, this latter situation is changing with the growth of managed care and a new sensitivity to the costs and benefits of medical therapies.

Ultimately, R&D investments in new medicines are very risky activities, governed by long-term expected returns. Our research at Duke further indicates that a small number of new therapies are critical to keeping the returns on drug R&D competitive with alternative investments of comparable riskiness. In particular, the distribution of returns is highly variable.[3] The search for new drugs is now centered around breakthrough therapies that can cover both the large fixed costs of R&D and the many unsuccessful compounds that are clinically investigated but never commercialized.

Effects of Government Controls

Government monopoly purchasing at below market prices significantly lowers the expected returns on new children's vaccines. It also reduces the cash flows available to undertake R&D investments in children's vaccines. New vaccines are supposed to be exempt from specific controls such as price caps. However, a firm undertaking investments of hundreds of millions of dollars over a decade or more to bring a new vaccine to the market must make these decisions on expectations about future market conditions. The VFC Program sends the message that the children's vaccines that are tomorrow's breakthroughs will have virtually no private market. Given the great uncertainty regarding the returns on and prices for these vaccines, one can expect R&D resources to shift to other therapies. The greatest negative effect would be on long-term discovery research. This research is the riskiest and furthest away from commercial introduction.[4]

The United States has been the acknowledged world leader in vaccine innovation, accounting for most of the new vaccines currently under development. Increased government control on vaccines will have especially negative consequences for smaller firms exploring new technologies. The biotech firms working on new vaccines have concentrated their R&D activity on long-term discovery research and are highly dependent on venture capital and external investment sources. It is important to emphasize that many of these firms are already operating with very stretched cash positions and burn rates on their R&D funds of two years or less.

A public policy goal of increased immunizations is very laudable. However, government programs targeted to at-risk populations are a much more effective and resource-efficient way to increase immunization rates. Government price regulation is a bulldozer approach to this societal problem that will have significant unintended negative effects on the incentives for research and development by biotech and pharmaceutical firms. Over the long term, patient welfare will undoubtedly be lower and healthcare costs higher if the private market for children's vaccines is eliminated under the VFC program.

Mr. BILIRAKIS. Thank you very much, sir.

Mr. Read.

STATEMENT OF J. LEIGHTON READ

Mr. READ. Mr. Chairman, I thank you for the opportunity to speak today. My name is Leighton Read and I am the chairman and CEO of Aviron, a privately owned pharmaceutical—biopharmaceutical company in the San Francisco Bay area, established 3

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[2] Bader, F. G. "Manufacturing Facilities Planning: Impact on Pharmaceutical Competitiveness," presented to MIT Symposium on the Future of the Pharmaceutical Industry, Cambridge, Mass., November 20, 1991.

[3] Grabowski, H. and Vernon, J. "Returns on New Drug Introductions in the 1980s," *Journal of Health Economics*, Volume 13, 1994, pp. 383-406.

[4] Grabowski, H. "Price and Profit Control, New Competitive Dynamics and the Economics of Innovation in the Pharmaceutical Industry," in the Office of Health Economics, *Industrial Policy and the Pharmaceutical Industry*, London, 1995.

years ago specifically to create a new generation of useful childhood vaccines.

Prior to founding this company, I was a faculty member at the Harvard School of Public Health and the Harvard Medical School, working on research on the cost effectiveness of drugs and other medical interventions, techniques that are now in use in evaluating all new medical interventions today.

For the past several years, I have been involved in the organization and financing of several successful biomedical startup companies.

The three points that I would like you to consider is that the Federal Government is sending the wrong signals to those who would invest private capital in creating new childhood vaccines. Second, that our immunization policy should not just look at today's vaccine but take into account a system of producing new vaccines and delivering them. Our immunization policy must take into account the rise of managed care systems which will soon enroll the majority of American citizens and childhood vaccine policies signal the way that we will reward successful innovators or many other critical areas of prevention beyond the vaccines for infectious disease.

I spend every day now talking to investors, attempting to interest them in vaccine innovation. The theoretical points made by my economist neighbor here on the panel are precisely the questions that I hear as I talk to investors who have choices between multimedia and telecommunications and fast food restaurants investment opportunities. Some of us in the room may have a passion for creating new vaccines. These people have to make choices and this Federal policy leading to a dominant role for the Federal Government in purchasing childhood vaccines is definitely having a chilling effect on interest in investing in this field. Where else in our economy do we ask the private sector to put several hundred million dollars at risk to develop a product which will be purchased by essentially one customer without the opportunity to negotiate price or terms in some form.

The concern is that a dominant government purchaser will not have any incentive to negotiate a fair price after the negotiator has taken the risk. Of course the States would like to have help buying vaccines with the purchasing power of the Federal Government and, of course, working parents would like to have free vaccines.

We should be focusing, as I said, on this continuing system of vaccine innovation and purchasing. Under the historical system of fee for service reimbursement and indemnity insurance, there were no economic incentives for anybody in the system to prevent illness. But with the rise of managed care, by the time Aviron's first products would reach the market in 1999, over 100 million Americans are going to be covered by some kind of capitated plan and these plans are very sophisticated buyers of health care and they are capable of performing the kind of cost effectiveness analyses that are now standard in the system.

Under this kind of scrutiny, vaccines to prevent infectious diseases compare very well with all the other choices that they are being offered so, as an innovator in this area, I would much prefer to negotiate prices with a marketplace of HMOs and State Medic-

aid programs, perhaps, or a plurality of many different buyers rather than a single dominant purchaser who will have lost the incentive to stimulate me to take economic risk.

The investors who support early stage research are exquisitely sensitive to the signals being sent from Washington and the case of Aviron illustrates what is possible in terms of cutting-edge research and also what is at risk. Our programs in the company address the institute of medicine's highest priority, virus vaccine targets including new vaccines for genital herpes, the virus which actually infects one in five Americans. Vaccines for respiratory syncytial virus, the most frequent cause of hospitalization in the very young and cytomegalo virus, which is the principal infectious cause of birth defects.

Our leading program could become the first practical way to prevent influenza in children, which is very important for working parents and for the rest of us because kids are so important in the spread of this epidemic. This is a program for a nasal flu vaccine being developed under a "CRADA" between Aviron and the National Institutes of Health.

We have raised a total of $17.5 million from venture capital partnerships. Their money is derived largely from U.S. insurance companies and pension funds so there are no villains or fat cats here, this is American capital working on projects that we would all like to see successful.

I believe that we can raise the other $120 million that we have to to bring Aviron's products to the point that the company could be self-supporting if the public policy is revised so that vaccine intervention is rewarded on a level playing field with innovation in——

Mr. BILIRAKIS. Please summarize, sir. Maybe you can't see the light there.

Mr. READ. Thank you, Mr. Chairman.

In conclusion, I would like to point out that this subject is larger than just childhood vaccines. It is important for us to get this policy right because the new biology is creating opportunities to prevent all sorts of diseases, theoretically anything. So who knows what opportunities to prevent heart disease and cancer and other sorts of preventive technologies that may now make economic sense under managed care. We need to create a policy environment that is supportive for those high-risk, long-term projects.

Thank you very much.

[The prepared statement of J. Leighton Read follows:]

PREPARED STATEMENT OF J. LEIGHTON READ, M.D., CHAIRMAN AND CEO, AVIRON, INC.

Mr. Chairman, Members of the Committee, thank you for the opportunity to speak today on the impact of the Vaccines for Children ("VFC") program on private investment in vaccine innovation.

I am Leighton Read, Chairman and CEO of Aviron, a three-year old biopharmaceutical company in the San Francisco Bay area established specifically to create a new generation of childhood vaccines for important viral infections. Prior to founding this company, I served as a faculty member at Harvard Medical School and School of Public Health where I conducted research on cost-effectiveness methodologies which are being applied today to determine whether new medicines and vaccines offer good value for money. For the past several years, I have been involved in the organization and financing of several successful biomedical start-up companies.

The three points I would like you to consider are that:

- The dominant role of the Federal Government in purchasing today's childhood vaccines is sending the wrong signals to those who would invest private capital in creating new childhood vaccines;
- Immunization policy must take into account the rise of managed care systems which will soon enroll the majority of American citizens; and
- Our national childhood vaccine policy is especially important right now because it signals the way we will reward successful innovators in many other critically important areas for prevention.

Currently, I am spending every day speaking to investors at large venture capital, mutual, pension and insurance funds regarding vaccine innovation in order to attract their interest in supporting Aviron's programs. One of the things which makes this difficult is government policy that unintentionally discourages, rather than encourages innovation in vaccines. By expanding the federal share of childhood vaccine purchases to over 80 percent, the VFC has reinforced the perception that the government arbitrarily limits the potential return on vaccine R&D.

Where else in our economy do we ask the private sector to put several hundred million dollars at risk to develop a product which will be purchased by essentially one customer, without the opportunity to negotiate price in advance? The concern is that a dominant government purchaser will not have an incentive to negotiate a fair price after the innovator has taken the risks of product development and regulatory approval. This fear of arbitrary confiscation runs deep, as I have personally heard senior pharmaceutical executives from large pharmaceutical companies say that they would not consider AIDS vaccine R&D because, if successful, "the government would just take it away."

Polices which emphasize only the "best price" for today's vaccines are seriously limiting the level of effort being devoted to vaccines for tomorrow's children—and ourselves. Policy now should focus on what is a continuing system of vaccine innovation, production, and utilization in light of two major environmental changes which are completely neglected by the VFC program: (1) the rise of managed care systems; and (2) the shift of biomedical innovation from large companies to small ones, with attendant need to attract private capital from investors who have confidence that development of successful vaccines will be rewarded in the marketplace.

Think about the economic incentives for prevention under the historical system of fee-for-service reimbursement to providers and indemnity insurance for patients. There was no dollar and cents advantage for patients, doctors, hospitals, or even insurance companies to keep people well.

Our health care system is now being dramatically restructured by market forces. By 1999, the year Aviron expects to market its first vaccine, over 100 million Americans will be enrolled in managed care systems. These HMOs and their capitated providers now have clear incentives to prevent illness. Through their formulary and practice guideline committees, HMOs are becoming very sophisticated buyers capable of analyzing the value of new prevention technologies side-by-side with new therapies. Increasingly, they are getting beyond concern with unit cost to the real issue of balancing cost and effectiveness.

Under this scrutiny, any innovative product or service can be thought of as falling into one of three categories. Least attractive are those which "buy health at a high price per unit of health," compared to interventions which "buy health at a low price per unit of health"—that is, those which provide good value for money. Only the rare product or service falls in a third category where its use actually lowers net health care costs and makes a contribution to health. By far the best examples of products in this category are vaccines for prevention of infectious disease.

As a vaccine innovator with a high degree of confidence that our products will offer excellent value for money, I would prefer to negotiate prices in a marketplace comprised of well-informed managed care buyers than with a dominant government purchaser. The VFC undermines this market. I understand there are managed care systems obtaining vaccine supplies at federally-controlled prices through their state programs. This does not make any sense if you want to encourage vaccine innovation.

There is a problem with leaving all prevention decisions to the HMOs. It is that their own investment time horizon may be limited to the average two to four year tenure of members within a given plan. This can be partially addressed through government and medical specialty society leadership on vaccine guidelines which are a component of the quality checklists being implemented as HMOs begin to compete on the basis of quality of care. We should also try to develop a system of transfer payments which reward HMOs for making investments in their member's long term health.

The second major environmental factor for vaccine policy is that the center of gravity in biomedical innovation has shifted from the large drug companies to small entrepreneurial companies such as Aviron. As the power of the "new biology" became apparent, there has been an unprecedented flow of billions of dollars of private capital into small entrepreneurial companies. These small companies have proven to be more effective in taking basic science discoveries to the next step. As a result, the large pharmaceutical companies are increasingly outsourcing the drug and vaccine discovery task, and concentrating on later stage clinical development and channels of distribution.

Biotechnology investors who support the early stage of vaccine innovation are exquisitely sensitive to the economic signals being sent from Washington. The large pharmaceutical companies must also see the rewards before they will invest in the large, expensive clinical trials required to bring a new vaccine to market.

Aviron's history illustrates what is possible in terms of cutting-edge vaccine innovation and what is at risk. Aviron was established in the San Francisco Bay Area in 1992, based on skills and patented technologies of my co-founders: distinguished virologists from the Mount Sinai Medical Center in New York, the University of Chicago, and the University of Alabama in Birmingham. Our programs address the highest priority virus vaccine targets listed in an Institute of Medicine Study. These include new vaccines for genital herpes (affecting one in five Americans), respiratory synctial virus (the most frequent cause of hospitalization in children under age two), and cytomegalovirus (the most important infectious cause of birth defects), as well as improved vaccines for influenza and chicken pox. Our leading program may become the first practical way to prevent influenza in children, which is especially important for working parents and the rest of us, because children are central to the spread of the epidemic. This vaccine is being developed via a Cooperative Research and Development Agreement ("CRADA") between Aviron and the National Institute of Allergy and Infectious Diseases, based on years of NIH-sponsored research and after a large pharmaceutical company lost interest in the project.

Aviron's initial funding of $2.5 million was provided by a small group of venture capital partnerships and individual investors with considerable biotechnology experience. In the ensuing year, we recruited key scientists, established our laboratories, and recruited a president with 20 years of experience at a leading U.S. company. Based on this progress, and a scientific R&D plan to create several new childhood vaccines, the company was able to accomplish a second private placement for $15 million in 1993. As before, most of the money came from venture capital partnerships whose funds are largely derived from U.S. insurance and pension funds, as well as university endowments. There are no fat cats or villains here; this is American capital at work on projects which everyone would like to see succeed.

People have invested in our company on the belief that further progress on Aviron's vaccine projects will make it possible for us to raise additional funds in private and public markets at progressively higher prices per share. Such an increase in value would be expected as risk is taken out of the portfolio of projects by successfully guiding them through research, pre-clinical, and clinical development.

In contrast to most biotechnology and pharmaceutical innovation, our strategy for profitability is based on high volume sales, rather than high prices, as we target a large portion of the population. Whether Aviron builds its own manufacturing and sales infrastructure or partners with a large pharmaceutical company that provides these elements, the availability of capital all along the way depends on perceptions of the ability to build future value by making progress towards commercially interesting markets. The reward will depend on the size of the market, product price, and the cost of making and selling each dose.

Aviron's investors have been persuaded that underlying changes in the health care system should create a favorable environment for preventive technology. We have argued that the coming years will see a shift in emphasis from a simple price concerns to value for money. Every study of vaccines I have reviewed show that, used as recommended, they are either net-cost savings to the system, or fall in the most desirable end of the spectrum value for money, comparing very well with nearly any therapeutic intervention in terms of health benefits purchased per dollar spent.

To bring the products in our pipeline to market, Aviron's programs will require further investment of an additional $120 million before we have the chance of supporting our R&D based on our own profits. I believe that we can raise the money, between equity markets and partnerships with large pharmaceutical companies, *if public policy is revised so that vaccine innovation is rewarded on a level playing field with innovation in therapeutics.* We must find a way to improve predictability of vaccine pricing so that innovators will not worry about having the fruits of their work mispriced simply because they are important. That is the only way that pre-

vention technology can compete with investment opportunities in multimedia, software, telecommunications or fast food restaurants.

There are other important issues, such as FDA reform, product liability, and federal technology transfer which can also accelerate the availability of new vaccines. I hope you will resist proposals to cut the budget of the Agency for Health Care Policy and Research, which performs valuable research on the cost effectiveness of medical interventions. Health services research, as well as the biomedical research enterprise embodied in the NIH's programs, are critical components of the "infrastructure" which enables a continuing stream of innovative vaccine technologies.

Mr. Chairman, the difficult decisions that the Committee must make over the next few weeks concerning revisions to the VFC program will have an important impact beyond the current subject, because the way we buy childhood vaccines in this country is a key economic signal for those who would commit private capital to other prevention technologies. Who knows which insights from the new biology will lead to vaccines for heart disease or various cancers? Let's make sure the system is set to reward the effort and enormous risks that will be required to bring such important innovations forward.

Aviron seeks to work with the Committee to develop a vaccine program that ensures a fair price for childhood vaccines. This, in turn, will ensure development of newer and more effective vaccines for this nation's children.

Thank you. I would be pleased to answer your questions.

Mr. BILIRAKIS. Thank you very much, sir.

Mr. Gordon.

STATEMENT OF LANCE K. GORDON

Mr. GORDON. Thank you, Mr. Chairman, members of the subcommittee.

By targeting for improved vaccine distribution and effectiveness through cost control, the VFC is compromising the very innovation that may in fact accomplish its initial objectives.

We look at some of the accomplishments over the past years of biotechnology, applied both in the biotechnology companies and the established pharmaceutical companies. They have included improvements in safety. There are I think 10 different types of vaccines in development that have much higher safety records. Effectiveness. If we look again at the effectiveness of many of the current pediatric vaccines, there is substantial room for improvement.

On a cost basis the hepatitis b vaccines have been brought down remarkably in cost through the application of recombinant DNA technologies.

The combination strategies being used which would reduce the administration costs, which we heard from the GAO is actually the largest portion of the cost associated with our vaccine problems, and efforts going on in other companies such as my own to reformulate vaccines as oral products which could avoid all of the cost associated with trained health care personnel.

I would just like to comment briefly on some of my background and particularly that in financing biotechnology companies. I've been in the vaccine business for 15 years, during which time I was the venturer of the hemophilus influenza b vaccine, mentioned earlier by the director of the CDC. I have also raised at this point over $100 million for companies of which I was CEO.

My thanks to the chairman here but my title is actually president and chief executive officer. I have a chairman who keeps an eye out on me.

OraVax has raised $38 million in private venture capital, that through many of the leading venture capitalists here in the U.S.

and internationally, including several governments, including the Belgian, the Singapore and the French governments.

Recently, we had the notable accomplishment of completing a public financing and raising an additional $23 million.

Having been on the road show for the past month, I think that gives me probably some of the most current and broadest experience with in fact what are the investors sentiments today. There is a very great concern that the government has specifically targeted for revenues reduction and margins reduction in the field of vaccines.

My background is pediatric vaccines, infant meningitis, protests and others. But we have found it necessary at OraVax in order to have the kind of development and growth we have had to target our products away from pediatric vaccines. My company is currently developing two adult vaccines and one preventative treatment product. These address viral pneumonia, ulcer, gastritis and antibiotic associated diarrhea. My experience has been that the investors are not willing to fund pediatric vaccine development.

That originates in the historical perspective on the vaccine industry. If we go back to the beginning of the 1980's when I entered the vaccine field, in 1980 the aggregate market for sales of DTP in the U.S., all manufacturers combined, was approximately $6 million and that was shared by nine manufacturers back in 1980. That is hardly an industry that can warrant the hundreds of millions of dollars necessary to bring a new product to market.

If you also look at what happened during the past 15 years in the vaccines industry in the U.S. some of the companies such as Merrill National, abandoned the vaccines before product liabilities was a driving force. They not only abandoned DTP but they wrote off as a tax loss, donated their entire facilities' product lines to the Salk Institute in that case.

Other companies such as GLAXO and Burroughs Wellcome more recently have not only abandoned DTP but all vaccines initiatives. We have a diminishing industry, an industry that needs the kind of opportunity incentives represented by a viable product area.

In the late 1980's, product liability problems thanks to the act of Congress, the 1986 Childhood Vaccine Injury Act, were satisfied. Also we had the introduction of new products. The hemophilus influenza b vaccine, proprietary products from two different manufacturers introduced in the late 1980's, hepatitis b vaccine penetration created new excitement.

Mr. BILIRAKIS. Please summarize, sir.

Mr. GORDON. I would just like to add one other major point. When we present this kind of a company and these kind of product objectives to the investors, the average venture capitalist in the U.S. receives 300 to 1500 business plans a year, 3 to 5 each and every day. They have standard criteria, one of which is a minimum 25 percent annual rate of return discounted for time to market. Given five business plans a day for many of these people, any business opportunity which government has formally taken the position that it will reduce the revenues and reduce the margins is the first one to hit the trash can.

My greatest fear is we have pushed this industry back to what it was in the 1970's.

[The prepared statement of Lance K. Gordon follows:]

PREPARED STATEMENT OF LANCE K. GORDON, PH.D., ORAVAX, INC.

A. Background

I'd first like to explain my qualifications to comment on the financibility of vaccine development. I have been in the vaccines industry since 1980, for seven years with Connaught Laboratories where I was the inventor of the first vaccine for infant meningitis (Hib), licensed in 1987, followed by a brief stint working on non-vaccine pharmaceutical products as an Associate Medical Director for Squibb in Princeton, and then back into vaccines in 1988 as CEO of a start up vaccines company, Selcore Labs which we took public as American Vaccine Corp., now known as North American Vaccine. In 1990 I started OraVax together with scientists and venture capital investors in Cambridge Massachusetts. Over the first five years we raised $38 million through five rounds of venture capital financing to support the development of new vaccines based principally on mucosal immunity. Last week OraVax had the notable accomplishment of completing a successful Initial Public Offering, raising an additional $23 million dollars in equity capital.

Earlier this year we announced the formation of a joint venture with Pasteur Merieux for commercialization of one of our product candidates, a therapeutic and prophylactic adult vaccine for *Helicobacter pylori*, the cause of ulcers and chronic gastritis. Under the jv OraVax and Merieux share equally the remaining costs of development and profits from sales world wide. OraVax continues the independent development of a prophylactic treatment product for infant viral pneumonia and a vaccine for antibiotic associated diarrhea, an adult vaccine.

My comments are based on my experience of developing vaccines with an established company and over the past seven years of financing vaccine R&D through private investors, professional venture capital investors, institutional investors and public investors. I believe that my comments are an accurate reflection of the perceptions of my peers in the Biotechnology industry and of the investment communities through whom we receive our financing.

B. Historical perspective

When I entered commercial vaccine development in 1980 the aggregate US market for the core pediatric vaccine, DTP, was approximately $6 million, a market that was shared by 9 manufactures. The price per 15 dose vial of vaccine at that time was less than $2.50. Some manufacturers were distributing their vaccines at a loss principally to get their catalogues in the hands of customers who might buy more profitable products. In the mid 1980's the industry was defending itself against excessive vaccine injury claims. While it remains unproven if the vaccine was responsible for the serious events it was well known that the vaccines induced fevers in as many as half of all recipients. Although the basis of many adverse reactions was well understood, changes in vaccine would have required several years of expensive preclinical research, clinical trials, changes in manufacturing procedures and amendment of facility and product licenses, incremental improvements could not be made. These requirements precluded implementing any but the most major changes in a product which would allow repositioning it in the market. Given the low profit margins for the products, the liability problems and the high costs of developing a fundamentally new DTP vaccine most of the manufacturers abandoned the effort. Of the nine commercial vaccine manufacturers we started the decade with, only two continued to manufacture and distribute the DTP product by the mid 80's. Some such as Merrill National, Glaxo and Burroughs Wellcome abandoned not only the DTP product but their entire interest in vaccines. As recently as last year Smith Kline Beecham contemplated exiting the vaccines business.

When I left Connaught in 1987 none of the US companies were expanding their vaccine businesses. Consequently I moved into the therapeutic drugs field at Squibb. In 1988 funding was established for the 1986 Childhood Vaccines Injury Act which limited product liability concerns and stimulated interest in renewed efforts toward vaccine development. Almost simultaneous events were market introduction of the Hib vaccines for childhood meningitis and growing market acceptance of the Hepatitis B vaccine, both of which were proprietary products with healthy gross margins. Sales of the DTP vaccine in the US had grown to almost $300 million. Although the larger sales were, due almost entirely to product liability generated price increases, the market was now large enough to justify efforts to develop new generation products. Based on the new opportunity I accepted the position of CEO of Selcore Laboratories, a startup company with the objective of developing a new, more effective and safer, DTP vaccine. Over the next two years we were able to attract a small amount of private financing, take the company public and raise the

capital necessary to produce and initiate clinical development of the product. During the past five years with OraVax we have been successful in raising both private and public equity capital to fund development of a pediatric treatment product and adult vaccines. In my experience, financing development of pediatric vaccines, which has never been easy, is virtually impossible today.

My biggest fear in regard to government efforts to reduce vaccine prices and make them commodity products is that the vaccine field will be forced back to the situation of the 1970's and much of the 80's; non-proprietary, undifferentiated products with low margins and little or no funding, either in the established companies or in biotechnology companies, for product improvement or the development of new vaccines.

C. Requirements for financing a biotechnology company

The ability to finance a pediatric vaccine in a biotechnology company is inseparable financing of the company. Since we don't generally have product revenues, our value is in the products under development. Investors have developed a set of criteria for funding biotechnology companies. These criteria are revised from time to time based on what is happening in the industry and in the stock market. The criteria are a concern to all investors, private individuals, professional venture capital firms, institutional investors such as insurance companies and banks, and public investors. The degree to which the criteria are applied is directly proportional to the stage of development of the company and the amount of capital needed for product development.

The company must be well differentiated from others. The average venture capital investor receives 300 to 1,500 business plans annually. Competition, entrenched positions of others and contentious intellectual property issues reduces the probability that the company will have time for successful product development.

There is tremendous opportunity for differentiation of pediatric vaccine projects in biotechnology companies from the established pharmaceutical companies. The reduction in the number of large companies in the vaccine field over the past 15 years itself has created the opportunity for new enterprises. In addition the established companies frequently suffer from entrenched technologies and product strategies. As in all other segments of pharmaceutical products biotechnology has created new opportunities.

A core proprietary technology capable of broad application. The technology of the company must have the capability of being applied to several products. Investors are all too well aware that any one product objective may fail.

There is a major move in the industry and in public health policy to move from vaccines for individual pediatric diseases to combination vaccines. This has the perceived public health advantages of reducing the number of separate injections, increasing compliance, reducing costs, and improving coverage. For the biotechnology company it may mean that they have no hope of actually reaching the market place on their own. In OraVax's case we have proprietary technology with the potential for developing an oral hepatitis B vaccine. However since efforts already well under way to combine Hepatitis B antigens with the DTP vaccine, it is impractical to develop the product alone. In fact in the past few years we have licensed a combination of DTP and Hib. New versions of any of the antigens in a combination product would likely not be accepted as stand alone products. The same applies to virtually any vaccine intended for routine pediatric use.

The products of the company must have the ability to generate a 25% to 35% annual rate of return based on a cash flow analysis discounted for time to market. The rate is set high because the time it takes to realize a return, competing investment opportunities and the proportion of investments that fail.

This is an area under direct attack by the governments efforts to control vaccine pricing. Investors can not and do not commit funds when there is not a annual discounted rate of return that meets their criteria. I have been directly told by several venture capital investors that they are convinced it would be impossible to have an acceptable rate of return for vaccines subject to government controlled pricing. When the President's plan to nationalize vaccine purchase and control pricing was announced, OraVax was in the process of completing a round of venture capital financing. In fact we had already received commitments from investors for the full amount of the intended financing, we had not however closed the round or received the money. Due specifically to concerns about government intervention, at least two of the investors withdrew their commitments. After much discussion, showing the investors that OraVax did not have any pediatric vaccine product objectives, and that the health care plan was specifically targeted to pediatric vaccines, we were able to bring back the commitments and complete the round as planned. Concern remains however that the pricing controls and bulk government purchase with its

deep discount demands may be extended to adult vaccines. On the road show for our IPO earlier this month several institutional investors continue to be worried about whether a successful vaccine, even if widely used, can achieve acceptable returns.

The investor must see a viable "exit strategy", how are they going to get their money out of the company. Venture capital investments are generally not liquid. There are three principal exit strategies today.

1) The biotech company will be acquired by an established pharmaceutical company.

Acquisition is viewed as a possible exit strategy. There have been a number of such acquisition in biotechnology broadly over the last year. Acquisitions in the vaccine industry include American Cyanamid's acquisition of Praxis in the mid 1980's, and Merieux's acquisition of Connaught. Within the past year American Home Products acquisition of Lederle-Praxis as part of the American Cyanamid acquisition. A review of which vaccine biotechnology companies have been acquired shows that they already had licensed products or significant products ready to enter the market.

2) The biotech company will go public so that investors can sell their shares on the open market.

Due to the failures of several biotechnology product development programs over the past year the hurdles to an IPO are very high. Today's minimum requirements include a well differentiated strategy, strong proprietary position, a broad range of product opportunity, specific product in clinical with some evidence of clinical efficacy, and a corporate partner to validate the product and help reduce the risks of commercialization.

3) The company will find a method to minimize the cash requirements to get to profitability and become self sustaining based on venture capital financing. Gains could then be realized through payment of dividends or ultimately through one of the above methods.

While every entrepreneurial company should strive to achieve profitability with the minimum dilution to its stock holders, the probability of developing a fully integrated pharmaceutical company based on venture capital financing is virtually nonexistent. Regulatory constraints, sometimes requiring multiple expensive phase III field trials and development of manufacturing facilities and staff, prior to proving that a product works in Phase III, are generally insurmountable barriers to going it alone. While the frequently cited numbers of $200 million are some what exaggerated for a typical vaccine, certainly $100 million to actual market introduction would be a great accomplishment. Venture capital investors rarely fund a company beyond an aggregate of $50 million and never for a single product.

The company must have products in advanced clinical trial, either already in phase III efficacy studies or with evidence of safety and activity in humans.

This is clearly not a requirement for start up companies, however it is applied stringently when a company is considering going public. Even earlier in product development it is a chicken and egg problem. Completing preclinical development and pilot manufacture of prototype lot meeting FDA requirements for initiating clinical trials costs at a minimum several million dollars. The company must have compelling data to attract the private financing to get to the clinical stage.

The company must have a corporate partner. Investors realize they are not competent to fully evaluate the validity of the companies technology or the commercial potential. They look to the established company to validate the technology. Venture capital investors realize they can not fund a project to market introduction, they look to the corporate partner for fully fund advanced development or at least to offset the cost of development.

Since many established companies have entirely left the pediatric vaccine field because of low profitability and product liability, and those that are left see the margins threatened by the federal programs, it is very difficult to attract a partner during early development.

The product opportunities of the company must have a positive pharmacoeconomics profile allowing a reduction in current health care system direct costs while retaining significant profit margins.

It is difficult to conceive of a pediatric vaccine that would not have a cost savings effect on the health care system. However with the efforts to minimize profitability of pediatric vaccines, it is difficult to see how a biotech can finance actual commercialization itself.

The potential for relatively short development time lines. A compelling argument must be made that the product has a potential for positive cash flow within an approximately five year period.

Development timelines for vaccine products are almost always over five years. Consequently the company must start out with a "seed" technology, such as a product already in development, or an inlicensed technology with already significant development history or be able to finance through the value of other assets.

D. Additional investor views of pediatric vaccines

Pediatric vaccines are not viewed as a special category by the investment community. Investors by definition are strict capitalists. The vaccines are subject to the same criteria and diligence as any other commercial opportunity.

The general perception is that vaccines have always been viewed as a weak segment of the pharmaceutical market. Traditionally they have been low margin products with several companies competing for market share. Investors are also very aware of the problems with vaccine injury liability that have plagued the industry, especially during the 1980's.

The general perceptions of investors are not significantly different from what we have encountered in Japan, a country with a vaccine industry similar to the US prior to the mid 1980's. I have spent three weeks in Japan meeting with investor groups and with sixteen Japanese pharmaceutical companies. Without exception when I discussed our interest in pediatric vaccines I have been told that they have no interest. This includes those companies who are currently manufacturing and selling pediatric vaccines in Japan. The products are viewed as government sponsored programs done as a public service. We have been referred for those products to institutes in Japan who themselves have sparse resources. In contrast the Japanese Pharma companies have been aggressively interested in our Helicobacter pylori adult vaccine, even there principally for its therapeutic activity.

E. Recommendations

Vaccines for Children—The US government should not have the ability to control pricing of vaccines differently than any other pharmaceutical product. As a related issue, the government should not increase the proportion of pediatric vaccines it purchases. It is an equally destructive way of lower prices and profit incentives and reinforces the consumers impression that vaccines are not very important "If its free, it must not be worth much". So long as investors believe that the government will control the return on investment potential for new or improved pediatric vaccines, it will be difficult to impossible to attract financing to a biotechnology company developing them. Their minimum include a 25% annual rate of return discounted for time to market. They will not invest in products with externally controlled margins.

The regulatory process in the US must be updated, particularly in regard to vaccines. The Center for Biologics Evaluation and Review (CBER) of the FDA requires that all biologic products, prior to marketing have not only a product license but also a establishment license—specific to each product. This regulation was created in because at the time of its creation most products, such as the whole cell pertussis vaccine were poorly defined products that could change their safety and/or effectiveness in unpredictable ways following even minor changes in production process. This standard is entirely inappropriate today. Many if not most vaccines today can be controlled by simple chemical, immunological or other modern laboratory assays. It should not be necessary today to regulate or control a product, beyond the GMP standards as applied to other pharmaceuticals, based on the geographical location of production, and details of production equipment. Defined products should be controlled based on the product, not the shape of the tank it was produced in. The establishment license requirement unique to vaccines and biologic products should be abandoned in favor of control based on product specifications as is routine practice for other pharmaceutical products.

An important corollary of the establishment license requirement is the policy that Phase III clinical trials done to obtain market approval must be done in the establishment to be licensed. This has required companies such as Zoma, Synergen, Repligen and many others to invest in commercial production facilities, often over $30 million in construction costs alone, prior to knowing if the products would work in the clinic. A much more acceptable regulatory approach is to continue requiring manufacture of clinical trial supplies in GMP compliance in an acceptable pilot plant and allow phase III studies with well defined product from pilot manufacture. Companies would then find it easier to get the capital to enter manufacturing on the strength of buying a product with proven utility. The regulatory objectives could be satisfied comfortably by requiring solid evidence of comparability of consistence lots from full scale manufacturing with retention samples of product used in the Phase III field trials. As needed small clinical studies can also be used to provide statistical proof in the target human populations that the product from pilot plant

and manufacturing plant are equivalent. *The uniform requirement for an establishment license for vaccines is a hold over from an earlier era. It represents the single largest hurdle a biotechnology company faces in advanced product development.*

Mr. BILIRAKIS. Thank you, Mr. Gordon.

Mr. Douglas.

STATEMENT OF R. GORDON DOUGLAS, JR.

Mr. DOUGLAS. Thank you, Mr. Chairman.

My name is Gordon Douglas. I am a physician, a specialist in infectious diseases, and I am president of Merck's vaccine business. I am also a member of the National Vaccine Advisory Committee.

I would like to focus my comments on what I believe has happened in the Nation's research and development efforts to bring new and wonderful vaccines to our children since creation of the Vaccine For Children's program.

We at Merck share the goal of full immunization for our Nation's children and we believe that many new, wonderful vaccines can be brought forward, such as vaccines for Lyme disease, herpes simplex and maybe some forms of cancer can be controlled. But all of this is dependent on a healthy national vaccine R&D climate and the VFC has seriously damaged that.

As you heard here on this panel, research and development on vaccines is primarily supported in three very different ways, first through taxpayer dollars that are used to support basic research at the NIH. Second, and the majority of vaccine research is done by private companies. Almost all of the technical expertise and some of the basic science resides in the private industry. And, finally, many new ideas are supported through smaller biotech companies.

What concerns me is that all three of these funding sources are in jeopardy. The Vaccine For Children's program will increase the public purchase, as we heard earlier, of vaccines from about 50 percent to 80 percent. The CDC estimates 77/23 split. Since a product such as our MMR, the discount for the Federal purchase is about 50 percent, you can see that the shifts in market due to VFC results in substantial reduction in cash-flow.

This point is critical, Mr. Chairman, because for several reasons intrinsic to vaccine R&D, a sustained long-term investment of resources is required to maximize the potential for innovation. It is cash-flow that drives our ability to fund vaccine R&D.

The Mercer study was initiated by the National Vaccine Advisory Committee by a resolution that recommends that the Secretary acquire a thorough analysis of the effect of the statutory price limitation under the VFC program on R&D. Our meetings with the Mercer Group were constructive, they were cordial and we were impressed with their understanding of the vaccine industry. The Mercer group was fully informed of the anticipated scope of the discussion prior to their visit.

Their report back to us at the second meeting was notable for the accuracy with which they portrayed the vaccine business, even in the absence of some information that we consider proprietary. Thus, the Mercer study has documented the financial dynamics of the vaccine industry in the United States.

The NVAC reviewed the Mercer study in our May 1995 meeting. Unfortunately, Mercer consultants were not allowed to predict the

program's effect on vaccine R&D, although they had a data base to do so. The administration's rationale was to wait until the exact percentage of public/private shift had occurred before calculating the effect on the vaccine industry. But the lead time to bring a new vaccine to market is 10 to 12 years at least. For chicken pox vaccine, it took 30 years.

Those investment decisions must be made now.

NVAC was convinced that Mercer's study would be helpful and requested that the Department authorize Mercer to continue its work and to specifically look at various potential scenarios such as 80/20, 70/30 and 60/40 splits between the public and private markets. I am pleased that Mercer is now prepared to supply this information to you. I am also convinced that Mercer's conclusions are valid. That tens of millions of dollars in vaccine revenues have already been lost to the vaccine companies as a direct result in the price restrictions in over 1993 and that hundreds of millions will continue to be lost year after year.

This situation, if allowed to continue over the long term, will inevitably discourage future private sector investment in discovering and developing new important vaccines.

Thank you.

[The prepared statement of R. Gordon Douglas, Jr. follows:]

PREPARED STATEMENT OF R. GORDON DOUGLAS, JR., M.D., PRESIDENT, MERCK VACCINE DIVISION

Good Morning. My name is Gordon Douglas. I am a physician, a specialist in Infectious Diseases, and I am President of Merck's Vaccine Business. I am also a member of the National Vaccine Advisory Committee. I would like to focus my comments on what I believe has happened to the Nation's research and development efforts to bring new and wonderful vaccines to our children since the creation of the Vaccines for Children Program.

We at Merck share the goals of full immunization for all our Nation's children and advancing health through new vaccines that work by preventing rather than treating diseases. Vaccines are the most cost-effective health care measures man has yet devised and there is great hope for new health achievements through vaccines in the relatively near-term future. In recent years, childhood meningitis has been nearly eliminated in the US and poliomyelitis has been eradicated from the Western Hemisphere. Combinations of existing vaccines will make administration of vaccines easier. New formulations of vaccines will eliminate many of the doses currently required, and diseases such as Lyme disease, Herpes simplex and some forms of cancer may be controlled. All this is dependent on a healthy national vaccine R&D climate.

The Vaccines for Children Program, I believe, has seriously impaired the Nation's effort. Let me explain. First, research and development on vaccines is primarily supported in three very different ways. One way is through taxpayer dollars that are used to support basic research on vaccines by several government agencies, primarily the National Institutes of Health. In addition, some development, particularly that which is not being done in the private sector is supported through the NIH. They do an excellent job.

Second, the majority of vaccine research and development in this country is done by private vaccine companies. In fact, almost all of the technical expertise, particularly in the area of process development, resides in private industry as does some of the expertise in basic science.

Finally, many new ideas are supported through the biotech companies. These companies raise funds from investors who are willing to invest in their ideas and bear the risk of failure. Many biotech companies fail, but some do bring forth important new ideas.

What concerns me is that all three funding sources are threatened. As we all know, the NIH budget is under severe stress at the present time, as are the budgets of many federal agencies. In the last two years, it has been more and more difficult for biotech companies to raise money from investors, particularly in the vaccine

area, because of the uncertainty in the market that has been created by the VFC program.

Let me explain further. Effectively, the Vaccines for Children Program will diminish the private vaccine market from about 50% to about 20% and increase the public purchase of vaccines from about 50% to 80% (CDC estimates 77/23 split). Since for a product such as Merck's M-M-R®II (Measles, Mumps, and Rubella Virus Vaccine Live), the discount for the Federal purchase is about 50%, you can see that the shifts in markets due to VFC results in a substantial reduction in cash flow. This point is critical, Mr. Chairman, because for several reasons intrinsic to vaccine R&D, a sustained long term investment of resources is required to maximize the potential for innovation. It is cash flow that drives our ability to fund vaccine R&D.

The Mercer Study was initiated by the National Vaccine Advisory Committee at its meeting on June 9-10, 1994, by a resolution that, "recommends that the Secretary acquire a thorough analysis of the effect of the statutory price limitation under the Vaccines for Children Program on research and development." The HHS response to this NVAC request was to contract with Mercer Management Consulting, Inc. to conduct an analysis of the economics of the United States vaccine industry. We at Merck agreed to participate in the Mercer Study because we share NVAC's concerns about the devastating impact of the Vaccines for Children Program on the US vaccine industry and our ability to remain at the forefront of discovery and development of innovative new vaccines.

Our meetings with the Mercer Group were constructive and cordial and we were impressed with their understanding of the vaccine industry. The Mercer Group was fully informed of the anticipated scope of the discussion prior to their visit.

We followed up the first meeting with further, less formal exchanges, including directing Mercer Staff to where relevant information is available in the public domain. For example, general costs of certain raw materials and other items which we purchase can easily be ascertained by contacting the supplier of those items.

Their report back to us at the second meeting was notable for the accuracy with which they portrayed the vaccine business, even in the absence of some information which we consider proprietary. We worked with Mercer to adjust several of their estimates but for the most part, we confirmed the accuracy of their work. In terms of the effects of the Vaccines for Children Program on vaccine research and development, it is our impression that the Mercer Group is comfortable with the information they obtained and the conclusions they have drawn from this information. Thus, the Mercer Study has documented the financial dynamics of the vaccine industry in the United States.

If released, the study will offer much needed insight into the realities of the vaccine business and will suggest once again the negative effects of the VFC program on the timely development of innovative new medicines upon which patients, parents, physicians, public health practitioners and ultimately children, have come to depend.

The National Vaccine Advisory Committee reviewed the Mercer Study at our May 1995 meeting. Unfortunately, while Mercer consultants were allowed to comment generally on the study which was done in the late fall of 1994, before VFC was fully implemented, they were not allowed to predict the program's impact on vaccine R&D although they had the database to do so. The Administration's rationale was to wait until the exact percentage of public/private shift had occurred before calculating the effect on the vaccine industry. But the lead time to bring a new vaccine to market is a ten to twelve year period at least. For chicken pox it took 30 years. Those investment decisions must be made now.

Research and development funding decisions are being made in vaccine companies and by investors in biotech companies today that could result in new products ten to fifteen years from now. NVAC was convinced that Mercer's study would be helpful and requested that the Department authorize Mercer to continue its work, and to specifically look at various potential scenarios such as a 80/20, 70/30 or 60/40 split between the public and private vaccine markets.

The NVAC resolution reads as follows: "We, the NVAC, recommend to the Director, NVP that the Mercer Consultants be instructed to examine the data and evaluate the effect of differing scenarios regarding the relative loss of private market due to VFC on vaccine company revenues and on research and development."

I am convinced that Mercer is now prepared to supply this information to you if asked. I am also convinced that Mercers conclusions will confirm that tens of millions of dollars in vaccine revenues have already been lost to the vaccine companies as a direct result of the price restrictions in OBRA '93 and that hundreds of millions will continue to be lost year after year.

It has been well-documented that vaccine companies behave much like pharmaceutical companies in terms of R&D investment and there are published studies

showing that 40% of top pharmaceutical revenue dollars are used to fund R&D; thus, it is easy to conclude that the effect of the Vaccines for Children Program on current vaccine R&D efforts in the US is both negative and substantial. This situation, if allowed to continue over the long term, will inevitably discourage future private sector investment in discovering and developing important new vaccines.

Thank you.

Mr. BILIRAKIS. Thank you very much, sir.

Mr. Grabowski, I have a series of maybe a couple of questions to you and then I am going to yield—after Mr. Waxman's time, I am going to yield the balance of my time to Mr. Greenwood.

Mr. Grabowski, did you sit through the entire day's proceedings?

Mr. GRABOWSKI. Most of them.

Mr. BILIRAKIS. You heard the GAO and you heard the CDC. I know you weren't here when we started this panel, but I mean prior to that.

Mr. GRABOWSKI. Yes.

Mr. BILIRAKIS. Do you feel that you have a pretty good familiarity with the program, the VFC program, in terms of the good that it is intended to do and that sort of thing?

Mr. GRABOWSKI. In a general way, not in all the detail.

Mr. BILIRAKIS. Not to take away from the statements made by all these other gentlemen, but you are with Duke University. It seems to me you don't have any axes to grind, and your statement to the effect that the VFC program would be and is very injurious to research and development of new vaccines is very telling, I think, to me.

Do you have anything to say in that regard? Keeping in mind that the good that the program is intended to do versus the harm that you indicated?

Mr. GRABOWSKI. As I say in my statement—I didn't get a chance to go into this—it is a very well-intentioned program. I think everyone shares the goals of increased immunization. But in terms of doing that in a cost-efficient way, one would say who are the people who are not being vaccinated and let's have a fine-tuned targeted program on that group. I think one would spend less resources and we would not have these long-term negative effects. It strikes me that there are lots of effects going on here. There are people who can afford vaccines, to pay for vaccines, will now in some sense get them subsidized or less.

There is a transfer there, there are resources that are needed in the public health in other dimensions that may get pulled into here and I don't think this is a well designed program and it has these long-term effects where we know that vaccines are an enormously effective, cost-effective technology, if we lose vaccines that can really have important effects on public health that we have lost in terms of long-term health care and health care expenditures.

Mr. BILIRAKIS. Thank you. Thank you, sir.

Would you mind if I yield to him? All right, then maybe we'll say about 8 minutes left, approximately, to Mr. Greenwood.

Mr. GREENWOOD. Thank you, Mr. Chairman.

I would like to address my questions to the gentleman from Mercer.

Wasn't your original assignment from HHS to study the impact of the VFC program on vaccine R&D investment?

Mr. HACKETT. That is correct.

Mr. GREENWOOD. Wasn't the revision in your assignment made only after you shared preliminary information with HHS that indicated the VFC program would have a significant impact on vaccine R&D?

Mr. HACKETT. That was the timing of the change. I can't ascribe motive to it because that wasn't said to me.

Mr. GREENWOOD. Who was it at HHS that contacted you and communicated that there is going to be a change in the nature of your assignment?

Mr. HACKETT. We were working closely with Dr. Roy Widdus was at that time acting director of the National Vaccine Program Office and he told us that Bill Core had made the decision to change the scope.

Mr. GREENWOOD. Who is he?

Mr. HACKETT. He works with Phil Lee, the assistant director; I am not sure of his title.

Mr. GREENWOOD. Did he tell you why Mr. Corr thought you should be making this change in your assignment?

Mr. HACKETT. He told us that they felt that the study was too speculative, that we were not being supplied with data on R&D from the suppliers and that we would have to speculate on that element of the study. We were also told that the amount of increase in Federal purchases was also a matter of speculation since we didn't know how many States would pass universal coverage laws nor how many doctors offices would actually implement the program.

Mr. GREENWOOD. Do you agree with those assessments?

Mr. HACKETT. Any time you look into the future, there is an element of estimation and projection that goes on. I don't think these elements were any different than the rest of our study where we had to look into the future or a lot of other work we do for clients to understand what may happen in the future so I don't agree.

Mr. GREENWOOD. You are familiar with what it is that the Congress intended when it directed this study be conducted. Did you consider HHS's new directive to you to be different than what was the intent of the legislation?

Mr. HACKETT. Yes.

Mr. GREENWOOD. Did you receive more compensation for the study than the original contract indicated?

Mr. HACKETT. Yes. The contract was extended through January and part of February for an additional fee.

Mr. GREENWOOD. So in other words, Congress said do A, Mr. Corr, whoever he is in HHS, said do B, and we will pay you more?

Mr. HACKETT. Well, the discussion of the extension of the study actually occurred before the meetings that you called into question where he may have felt that the outcome was against what he would like to have seen. The purpose of the extension was that the study was wrapping up around the Christmas time period and a lot of people at CDC who we needed to meet with to discuss the findings were unavailable and they wanted to push the study into January and February in order to have adequate time to review our findings and to have comment on them and to reflect those into the final report so I don't think those two things were related.

Mr. GREENWOOD. In your experience, is it unusual for the results of your work to be censored by the party with whom you contract?

Mr. HACKETT. It is unusual but not unheard of.

Mr. GREENWOOD. Do you think that is a fair characterization of what happened?

Mr. HACKETT. I would have to speculate on and the timing of the change in the modification seemed very coincident to us with a series of reports that we filed that were not popular.

Mr. GREENWOOD. Do you find it particularly unusual to experience editorial control of your product under a government contract that is financed by the taxpayers?

Mr. HACKETT. That occurred to me as well, yes.

Mr. GREENWOOD. Would you be inclined to contract with HHS in the future?

Mr. HACKETT. If the job was necessary, yes.

Mr. GREENWOOD. I understand that there is some speculation involved in what happened here. What does your gut tell you happened here?

Mr. HACKETT. My gut tells me that we said some things that people didn't like to hear.

Mr. GREENWOOD. People at HHS?

Mr. HACKETT. CDC, HHS, yes.

Mr. GREENWOOD. Is it your belief that if you had followed the study that the Congress asked you to follow, that this program was going to have a very deleterious effect on vaccine R&D and the folks in CDC and HHS would just as soon that that information would not be public? So they redirected their study. Is that what your gut tells you?

Mr. HACKETT. That would be my speculation.

Mr. GREENWOOD. Thank you, Mr. Chairman.

Mr. BILIRAKIS. Actually, that is the 5-minute clock, so you really have another 2, 2½ minutes.

Mr. GREENWOOD. Mr. Chairman, he said everything I wanted him to say. Thank you.

Mr. BILIRAKIS. Mr. Waxman.

Mr. WAXMAN. Thank you, Mr. Chairman.

Just for the record, the Congress did not direct this study. Congress directed the secretary of HHS to ascertain whether the statutory limitation on prices for current vaccines allows for sufficient research and development studies and then to give us her guidance as to whether the law ought to be changed.

Mr. Hackett, when you discussed your study with the public health service, wasn't it your impression that the public health officials wanted your analysis to be completed and in fact didn't Dr. Lee, the Assistant Secretary for Health back up your own request to the vaccine manufacturers by a letter requesting that they work with PHS to develop a mechanism to ensure that this important information be provided?

Mr. HACKETT. I don't have any awareness of Dr. Lee doing that prior to January when the scope of the study was changed. The knowledge I have of Dr. Lee's contacting the manufacturers was in March when he at that time was trying to get information from them.

Mr. WAXMAN. He wanted you to get raw data from the companies themselves and you didn't have that information, isn't that correct? You didn't have the actual data from the company?

Mr. HACKETT. We didn't have the data from the companies.

Mr. WAXMAN. He thought you ought to have the data from the companies and he suggested he wanted you to complete your report but with that further information and I have for the record, Mr. Chairman, Dr. Lee's letter.

[The letter follows:]

DEPARTMENT OF HEALTH & HUMAN SERVICES,
OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH,
April 4, 1995.

R. GORDON DOUGLAS, JR., M.D.
President, Merck Vaccine Division, Merck & Company, Inc.
P.O. Box 100, Whitehouse Station, New Jersey

DEAR DR. DOUGLAS: In response to a resolution of the National Vaccine Advisory Committee (NVAC), the National Vaccine Program Office (NVPO) has contracted with Mercer Management Consulting, Inc., to conduct a study of the economics of the U.S. vaccine industry. I am writing you now to express my concern that Mercer has not been able to collect reliable data to support any conclusions about your company's research and development budget and future R and D expenditure plans.

The goal of this study was quite ambitious. We wanted to develop an accurate understanding of the economics of the U.S. vaccine industry and an accurate picture of the effect of the OBRA 1993 legislation on U.S. vaccine manufacturers. The NVAC was particularly interested in determining how vaccine company research and development budgets might be affected by an increase in the volume of government vaccine purchases and the statutory limitation on the price the government can pay for vaccines.

As you know well, an evaluation of pharmaceutical company research and development activities involves many complex factors, such as, scientific opportunity, company capabilities including changes in revenue, assessment of potential product market, opportunity costs and potential liability. Our expectation with this study was that Merck would share sufficient data and information about your research and development activities and plans to enable Mercer to do more than speculate about the effect of OBRA 1993 on your company. Both NVPO and Mercer wrote Merck requesting your support for this study. While I understand that Merck's representatives have spent significant time with Mercer, I also understand that Mercer has not received data and information about your research and development activities that would allow Mercer to make an independent quantitative assessment of the effect of OBRA 1993 on your company. As a result, Mercer's report will not contain any analysis of how Merck's research and development activities might change.

The Mercer study will enhance the understanding of important facets of the vaccine industry. However, I am unwilling to consider the Mercer study complete until I have made every effort to further the understanding in this most critical area of inquiry.

I would like to work with you to determine a method by which Merck, and the other vaccine companies, can share the critical data and information needed to fairly assess the impact of our current vaccine purchase practices on vaccine research and development efforts. I would appreciate your consideration of how we might proceed. I will be calling you soon to discuss this matter.

This Administration is strongly committed to preserving and expanding our nation's vaccine manufacturing and research capacity. American children, and children throughout the world, deserve nothing less than our best effort to continually produce and make available vaccines for preventable childhood diseases.

Sincerely yours,

PHILIP R. LEE, M.D.,
Assistant Secretary for Health.

Mr. WAXMAN. I am mystified by this concept because it seems to me that contrary to the notion that the program stops the potential market, the reverse is really true when the government finds that there is a promising vaccine and then mandates it. There is a clear market because of the government requirement that every child be

immunized when a new vaccine is approved. If the company sells its new vaccine, it is doing so without having to market it. They don't have to promote it. There is a clear market available to them without any effort on their part. The company sells its new vaccine at its launch price without a single penny of investment in marketing. Let's assume, for example, that if the government is buying 60 percent of the total market, if the recommendation is that every new baby receive a single dose of this new vaccine, the government is then required to purchase about 2.1 million doses of this new product. To me this does not sound like a declining market, it sounds like a guaranteed market for 2.1 million doses.

What is your view of this argument?

Mr. GRABOWSKI. Well, it is a question, yes, there is a market, but at what price. I think what happens, you said that they will sell at their launch price. What happens is, there is a recommendation and CDC will put forth an RFP to the company and then there will be a negotiation process.

Generally where we see that there is only a single buyer, the government buying a product, it is very seldom that that price is a private market price. What I think is fearful of venture capitalists and other people that would finance this is that looking down the road, if you see only a government market, that you will have something like public utility regulation down the road, or at least a heavily discounted price, a commodity price.

I think there is a lot in economics that shows where you have only the government purchasing that they tend to purchase at a price that doesn't make you want to invest in risky activities over a long period that would then hope that you could get a return.

Mr. WAXMAN. Isn't it true whenever you talk about vaccines, you are talking about generally a government purchaser as the major purchaser of a vaccine?

Mr. GRABOWSKI. Well, 10 years ago it was 30 percent, and then it has been 50 percent. I think everyone would acknowledge that the government should be a major purchaser, but managed care and other institutions could also be purchasers. You could have a plurality of a market so you could negotiate with several entities.

Mr. WAXMAN. Thank you very much.

My time has expired. I had other questions.

Mr. BILIRAKIS. Without objection, I would be glad to yield another 1 or 1½ minutes.

Mr. WAXMAN. It's all right.

Mr. BILIRAKIS. Mr. Norwood.

Mr. NORWOOD. Thank you, Mr. Chairman. I am very disappointed for myself that I missed a lot of the hearing today because of some activity on the floor.

I realize we addressed a great number of issues. I do hope somebody today determined how many vaccinations this country provided and at what cost for each vaccination through this day's efforts.

Dr. Douglas, in your testimony you state that the National Advisory Committee in 1994 recommended that an analysis be conducted on the effect of the statutory price limitation on research and development. In response to this request, HHS contracted with Mercer to conduct a study on the economics of the vaccine industry

in the United States, and Mercer then presented the preliminary findings demonstrating that there was a negative effect on research and development on new vaccines. Then HHS killed that part of the study. That is as I understand it.

First, would you please comment on the quality of the economic analysis that Mercer has so far performed on vaccine R&D?

Mr. DOUGLAS. Yes. Congressman Norwood, thank you very much. I believe that the quality of the Mercer study is excellent. While we did not divulge certain kinds of highly proprietary information, we did divulge a lot of other information, and there is a lot of information given in publications, annual reports, and they use cross-checks and verifications.

There was a full scale meeting with them. I hooked them up with different people in the organization who could supply various kinds of information with them over a 10–12 week period of time. There was a lot of personal communication.

Then there was a second debriefing of their information for us at which time we were able to point out things that we felt were incorrect or were correct in their analysis, and point them to sources of public information which would give them the precise piece of information.

For example, our No. 1 small thing was, they had a price for a glass vial that we use which was much less than the glass vial we actually use because we use a very high quality vial for our vaccines. I was able to point to the supplier of our vials, and they were able to find it. You know, there is a catalogue and they could look up what the price is.

A lot of the information, you would be surprised, is publicly available, and by carefully pointing that out for them, we were satisfied that they had done an excellent job, and certainly the final results of their study jived very closely with our internal analysis of the financial dynamics of the vaccine business.

Mr. NORWOOD. Well, could you further comment then, why do you think the R&D study was so abruptly ended by HHS?

Mr. DOUGLAS. Well, I think that, as Mr. Hackett has already testified, I believe that the department did not like the results because they were told that there was a negative effect of the VFC, and they didn't want to hear that. That is my opinion. I don't have any other basis for that.

Mr. NORWOOD. Dr. Grabowski, do you agree generally?

Mr. GRABOWSKI. From my knowledge of the facts, it sounds like that is the case, but I am not an insider in the issue.

Mr. NORWOOD. Does anybody want to take a guess as why they didn't want to hear it?

[No response.]

Mr. NORWOOD. Did it not suit their plans, or did they want to make sure the public didn't know?

Mr. WAXMAN. Will the gentleman yield?

Mr. NORWOOD. Yes, sir.

Mr. WAXMAN. I have a letter that I put in the record, and Dr. Lee wrote to Dr. Douglas asking for information from Merck about how much they spent on vaccines, research and development. I think he wanted to have that information.

Mr. Douglas, why can't we have that information available to the contractor for the department, or maybe this committee, or the government of the United States in order to make the decision as to whether there is a decline in R&D dollars. Why can't we know what the R&D dollars are in the first place?

Mr. DOUGLAS. There are several reasons why some information cannot be divulged. One is, it is proprietary information, it would give our competitors advantage if they knew what we were doing in certain areas and we are not going to let that information out.

There is a great deal of information that is in our annual report. For example, the total research spent, the sales of vaccines on an annual basis are in the annual report. That information is available.

So the numbers are very, very accurate in the Mercer report.

Mr. WAXMAN. Mr. Chairman, I would like to ask consent for 1 minute?

Mr. BILIRAKIS. Without objection.

Mr. WAXMAN. I just want to read this paragraph of this letter to you, Dr. Douglas, which I am sure you have already read yourself. Dr. Lee said: "As you well know, evaluation of pharmaceutical company research and development activities involves many complex factors such as scientific opportunity, company capabilities including changes in revenue, assessment of potential product market, opportunity costs and potential liability. Our expectation with this study was that Merck would share sufficient data and information about your research and development activities and plans to enable Mercer to do more than speculate about the effect of OBRA 1993 on your company."

He wanted you to get that information. As I understand it, he wanted Mercer to have that information, accurate information, not to speculate but to have accurate information. What was your response to him?

Mr. DOUGLAS. Well, Congressman Waxman, I did write a letter back to Dr. Lee, and I discussed it with him personally. I believe that we supplied sufficient information so that Mercer could calculate the financial dynamics of the industry, and I believe they have captured that. I think that is my answer.

Mr. WAXMAN. I guess there is a dispute as to whether he thought he had enough information.

Thank you, Mr. Chairman.

Mr. NORWOOD. Mr. Chairman, may I have unanimous consent to have 2 minutes of Mr. Waxman's time?

Mr. WAXMAN. Why didn't you just ask for 2 minutes.

Mr. NORWOOD. Because it was fun asking it that way.

Mr. BILIRAKIS. Without objection, of course.

Mr. NORWOOD. Apparently, the HHS said that it was too speculative, but was the lack of information concerning pricing, was that any more speculative than any other part of a study when you are trying to reach out there and estimate what is going to happen for the government?

Mr. DOUGLAS. Congressman Norwood, I think that from my discussion with Dr. Lee, what they were concerned about was the speculation of what the market would be like in the future. What was the split going to be. One of the purposes in my testimony was

to say, we are making research decisions today and yesterday and tomorrow about what kinds of products were are going to have in 10 to 12 to 15 years.

We can't wait until what the VFC is going to look like exactly next year. We have to speculate, and we are in a position of taking a more constrained posture to making those decisions because it looks as if the private market is going to be substantially reduced, the public market is going to be substantially increased, but with a net decrease in cash-flow which is the fundamental driver for these decisions.

Mr. NORWOOD. One last quick question. Under the statute new vaccines are not covered by the price cap which is applied to old vaccines. Do you think this exclusion will have any positive impact on the development of new vaccines?

Mr. DOUGLAS. I think that the fundamental problem is that there is an uncertainty that has been created in the market, and an uncertainty of the extent of government control of the industry. While there is some freedom to price new products within a market environment, it is not really a market environment, and you really don't have total freedom for pricing. I think that that is the fundamental problem, that they really have changed the perception of the marketplace and how investors in small companies and boards of directors in large companies will allow you to put money into R&D.

Mr. NORWOOD. It is an understandable thing to me, what you state. I would be very nervous, too, if the government that is often very fickle and changes its mind every few years about what we will and won't do, if they were my only purchaser.

Mr. Chairman, it reminds me a little bit of a brother-in-law I have who makes shirts. The one thing they do know is, they do not want to sell all their shirts to Sears because as soon as they do, Sears starts twisting down on what they will pay for shirts, and you are shortly at the mercy of the buyer of shirts in terms of what they will pay for them.

I have a little bit of a feeling you might be in a similar situation here.

Mr. DOUGLAS. It feels about the same, yes.

Mr. NORWOOD. I'll bet so.

Mr. BILIRAKIS. I thank the gentleman whose time has expired.

Dr. Douglas, do you have a copy of the letter, your response letter, to Mr. Lee?

Mr. DOUGLAS. Yes, I do.

Mr. BILIRAKIS. Would you submit that?

Mr. DOUGLAS. I would be very happy to supply that to the committee.

Mr. BILIRAKIS. Without objection, that will be a part of the record.

Without objection, the briefing materials prepared by Mercer for the December 20, 1994, National Vaccine Program Office meeting and the final Mercer report issued to HHS on June 14, 1995, this year, will be made a part of the record.

[Information not received at time of publication.]

Mr. BILIRAKIS. I just have one final question. The conversation you had with Mr. Lee, you said you responded in writing to his let-

ter, his April letter, and you also had a personal conversation with him. What was the atmosphere of that conversation? Can you share that?

Mr. DOUGLAS. I've known Dr. Lee for a long time. We have a good personal relationship. The atmosphere is friendly, but we fundamentally disagreed on this issue.

Mr. BILIRAKIS. You did continue to disagree?

Mr. DOUGLAS. Well, I think that Dr. Lee understood that I felt that they had sufficient information to formulate an analysis of the financial dynamics of the vaccine industry, and he was surprised when I told him how much information we really had given to the Mercer people. I think that his people had told him that there was much less than we had actually supplied.

Mr. BILIRAKIS. All right. Thank you.

Mr. Bryant.

Mr. BRYANT. Thank you.

Dr. Douglas, have you recently tried to raise money, equity capital, or borrow money and been unable to do it because of the government program?

Mr. DOUGLAS. No, sir, but we don't fund from equity markets.

Mr. BRYANT. Well, you were talking about investor confidence here.

Mr. DOUGLAS. I think my colleagues from the smaller companies could better address that.

Mr. BRYANT. Well, let me ask you about one of the smaller companies. I see here that Smith Kline Beecham and North American Vaccine who, for some reason, we didn't hear from today are walking around Capitol Hill talking to Members of Congress saying they support the program. I would think they would be a good deal more capital sensitive than anybody at the table here today.

Is that a fair assumption? I am asking Dr. Douglas.

Mr. DOUGLAS. I don't know what they are walking around the Hill and saying.

Mr. BRYANT. I just told you what they are walking around the Hill saying. I'm asking you, isn't it a fair assumption that they would be a good deal more concerned about capital markets than a company like Merck?

Mr. DOUGLAS. No. Smith Kline Beecham is in the same ballpark as we are in terms of being a fairly well-established pharmaceutical company. North American Vaccine is a small company.

Mr. BRYANT. Then what are we talking about here when you talk about investor confidence? I mean you have got all the capital you need to do the R&D you are doing, you have all the capital you need to expand. I assume your stock price hasn't dropped, or maybe I am wrong about that, and you can tell me. I assume you think it is a good investment. So what are we talking about when you talk about investor confidence?

Mr. DOUGLAS. Well, Congressman Bryant, I think, as I made the point, it is not capital that funds research in the larger companies, it is cash-flow. Cash flow is due to sale of product. What I am saying is that the cash-flow is being decreased because of the shift from the private to the public market of about 50/50 to about 80/20, and with the reduction, as just an example, Merck's MMR is a 50 percent price decrease to the Federal Government, so we have

lost 50 percent of the price on 30 percent of the market. It is a very simple calculation to figure out how much money that is.

Mr. BRYANT. Shouldn't we really be talking about how much more money we need to be paying in order to keep you fellows able to spend enough money for R&D? It is just a question of pricing, isn't it?

Mr. DOUGLAS. Yes. Had the price not been capped at the time the market shift occurred, there was a lot of discussion back in 1993 about this, that if the prices had been able to be changed—that is, the discount would not be so great to the Federal Government so that we could remain cash-flow neutral, if I can use that expression—we would not be seeing the same kind of effect on negative R&D in the marketplace, a negative effect on R&D that we see today.

Mr. BRYANT. Let me ask you another question. The companies that win State Medicaid managed care contracts like Aetna, Prudential and Blue Cross, are they likely to get the same price for a smaller volume of vaccine purchases that they would make presumably under these block grant programs as the Center for Disease Control now gets for the large volume that it buys under the vaccine program?

Mr. DOUGLAS. Congressman, large volume purchasers generally get a lower price than single vial purchasers, for example, yes.

Mr. BRYANT. Would that not then raise a serious question about the wisdom, from the standpoint of a government that is trying to make sure its little kids are vaccinated, itemizing this program into 50 pieces and giving everybody a block grant and let them all go out and negotiate for themselves? It would be cheaper, would it not, to buy it from one place than to buy it from 50 different places?

Mr. DOUGLAS. Well, it might be cheaper to buy it from one place than from 50 or 100 different places, but it is destructive to the marketplace and destructive to research and development in the future. We, for example, would rather deal with a multiple marketplace, and I think other people on this panel have testified to the same thing, whether it is multiple HMOs, States, Federal Government, whoever.

It seems to me that the VFC is misdirected in spending most of its money on vaccine purchase and nobody can convince me that 80 percent of the children in America are impoverished. There is a certain number, and we need to focus attention, we absolutely need programs that will ensure that impoverished children in innercities and rural areas wherever they are, get vaccinated.

Mr. BRYANT. Well, tell me if I am wrong, but isn't that the situation we had before the vaccine program came along, this multiple market situation?

Mr. DOUGLAS. That's correct.

Mr. BRYANT. Well, but we didn't have every vaccinated?

Mr. DOUGLAS. Well, actually, the problem prior to VFC was not that there wasn't a large public purchase of vaccines. Prior to VFC 50 percent of the vaccine was purchased publicly and was available free of charge to any person in the United States of America who chose to go to a public health clinic. There was plenty.

There has never been a supply problem. There is plenty of free vaccine out there. The issue is all the other things we have heard about, outreach, clinics, sufficient number of clinics, keeping patients in doctor's offices, those kinds of things that have been identified many, many times, and that is where the focus should be in my judgment.

Mr. BILIRAKIS. The gentleman's time has expired.

Gentlemen, thank you so very much for taking the time and for staying all day long and understanding the situation here. We have learned a lot from you. Thank you so much.

Mr. DOUGLAS. Thank you very much.

Mr. BILIRAKIS. Our final panel consists of Dr. Elin Gursky, Senior Assistant Commissioner of Health for the State of New Jersey; Mr. Robert Goldberg of the Gordon Public Policy Center at Brandeis University; Dr. David Smith, Commissioner of the Texas Department of Health who is testifying on behalf of the Association of State and Territorial Health Officials; Dr. Louis Cooper, Director of Pediatrics at St. Lukes Roosevelt Hospital Center in New York who is testifying on behalf of the American Academy of Pediatrics; and Mr. James Weill, General Counsel of the Children's Defense Fund.

As with the others, your entire written testimony is a part of the record, and I would ask all of you to please limit your testimony to 5 minutes, and we will start out with Dr. Gursky.

STATEMENTS OF ELIN GURSKY, SENIOR ASSISTANT COMMISSIONER OF HEALTH, STATE OF NEW JERSEY; ROBERT M. GOLDBERG, GORDON PUBLIC POLICY CENTER, BRANDEIS UNIVERSITY; DAVID R. SMITH, COMMISSIONER, TEXAS DEPARTMENT OF HEALTH, ALSO ON BEHALF OF ASSOCIATION OF STATE AND TERRITORIAL HEALTH OFFICERS; LOUIS Z. COOPER, DIRECTOR OF PEDIATRICS, ST. LUKES ROOSEVELT HOSPITAL CENTER, ALSO ON BEHALF OF AMERICAN ACADEMY OF PEDIATRICS; AND JAMES WEILL, GENERAL COUNSEL, CHILDREN'S DEFENSE FUND

Ms. GURSKY. Thank you. Chairman Bilirakis and members of the committee, my name is Dr. Elin Gursky, and I am the Senior Assistant Commissioner of Health for the State of New Jersey. I thank you for the opportunity to express my concerns about the Vaccines For Children Program.

The nationwide epidemic of measles and mumps in the late 1980's demonstrated the failure of many systems to protect this country's children from vaccine preventable diseases. In summation, these shortfalls included the failure of public health clinics to be geographically and temporally accessible to the community they serve; the failure of clinicians, both in the public and private sector, to ensure that every visit to a medical care provider was an opportunity to review and update vaccination status; and the failure of mothers and fathers and the failure of mothers and fathers to make appropriate and timely immunization a sacrosanct activity of the parenting role.

From my perspective, the VFC Program is doing little to correct these failures. The VFC Program, which makes vaccines available for distribution to private and public physicians, does not focus on

the right problem. The problem is not supplier costs but rather the need to improve access and outreach.

The Vaccines For Children Program does not address the large number of physician providers who do not wish to participate in the program because of low remuneration for office visits and other VFC administrative requirements. In other words, even though the vaccine is free, the paperwork involved may be a disincentive for physicians to participate.

The VFC Program does not address the numbers of children who, by benefit of this program, become fully immunized. The goal of our immunization effort is to achieve 90 percent of infants being completely vaccinated by age 2 years. A VFC participating physician must report the numbers of vaccines administered, not the number of children brought to full immunization. An infant must receive 15 shots over four to five visits to be fully protected against polio, diphtheria, measles and other vaccine preventable diseases.

The Vaccines For Children Program does not address the burden on health departments to receive, warehouse, properly refrigerate, distribute and inventory thousands of doses of vaccine. We feel public health resources can be put to better use.

Just because a vaccine is available does not mean that parents will bring children to the clinic, that children will be properly immunized by their care provider, or that State officials will have accurate immunization data to improve immunization strategies.

Now, in response to the measles epidemic, the Centers for Disease Control took aggressive measures to hold each State accountable to determining its immunization needs and strategies. The CDC wrote standards for pediatric immunization practice as a guide and blueprint to develop higher immunization rates. Limitations in public health infrastructure were identified, and each State produced an immunization action plan which identified objectives, processes and time lines for improving the numbers of infants fully immunized.

In New Jersey, we have used the immunization action plan to build a system to provide for good immunization assessment for on-site vaccine available to children enrolled in WIC and AFDC programs, to co-locate immunization and WIC services, and to develop an electronic immunization information data base linking the histories of patients attending WIC, AFDC, hospital pediatric clinics, and private physician offices.

There are, therefore, important immunization program needs other than the bulk purchase and distribution of vaccine which may be short-changed because of the redirection of money and efforts to the VFC Program. There is a need to sustain and increase funding to the State immunization action plans which allow each State the flexibility to design and implement an immunization program based upon its own unique sociodemographics and immunization needs. It facilitates our ability to identify and bring into partnership many important public and private players who will have a stake at living in communities with little threat of outbreaks from vaccine preventable diseases.

Immunizing children is not a vaccine supply problem. If the latter were true, this country would not have 95 percent of all children appropriately immunized by kindergarten. This rate is a tes-

tament to the gatekeeper approach of requiring shots before school entry that demonstrates that vaccination is attainable. This high percentage of fully vaccinated younger children in most States now requiring immunization for preschool and day care entry in receipt of Federal support in programs such as WIC and AFDC.

Mr. BILIRAKIS. Please summarize, doctor.

Ms. GURSKY. Immunizing children is about outreach, access, recall, reporting and surveillance as well as providing incentives and penalties.

In summary, to sustain high rates of infant immunization, we must put functioning systems into place. Thank you.

[The prepared statement of Elin Gursky follows:]

PREPARED STATEMENT OF DR. ELIN GURSKY, SENIOR ASSISTANT COMMISSIONER OF HEALTH, STATE OF NEW JERSEY

Chairman Bilirakis and Members of the Committee, my name is Dr. Elin Gursky and I am the Senior Assistant Commissioner of Health for the State of New Jersey. I thank you for the opportunity to express my concerns about the Vaccine For Children (VFC) Program created by the Omnibus Budget Reconciliation Act of 1193.

Let me first share with you a bit of my background. As a Senior Assistant Commissioner of Health, I am responsible for the Divisions of Epidemiology, Environmental and Occupational Health Services, and Public and Environmental Health Laboratories. I received my training in Epidemiology and Public Health from the Johns Hopkins University, where I hold appointments in the Schools of Medicine and Public Health and Hygiene. I have developed and taught graduate work in Public Health Practice, designed to teach physicians and health care providers both the art and science of making good community medicine decisions based on biologic, economic, cultural and other factors. From 1986 to this past March, I was Director of the Division of Epidemiology and Disease Control for Prince George's County, Maryland. Additionally, for the past four years I served as Chair of the immunization Task Force for the Metropolitan Washington Council of Governments representing Northern Virginia, Suburban Maryland, and the District of Columbia. It is from these perspectives I can speak to the challenges of trying to immunize children.

The nation-wide epidemics of measles and mumps in the late 1980's demonstrated the failure of many systems to protect this Country's children from vaccine-preventable diseases. In summation these shortfalls included:

—the failure of public health clinics to be geographically and temporarily accessible to the community they serve;

—the failure of clinicians, both in the public and private sector, to ensure that every visit to a medical care provider was an opportunity to review and update vaccination status;

—the failure of mothers and fathers to make appropriate and timely immunization a sacrosanct activity of the parenting role.

From my perspective, the VFC program is doing little to correct these failures. The VFC program which makes vaccine available for distribution to private and public physicians, does not focus on the right problem. The problem is not supply or cost, but, rather, the need to improve access and outreach. The VFC program does not address:

—the large numbers of physician providers who do not wish to participate in the VFC program because of low remuneration for office visits, and other VFC administrative requirements. In other words, even though the vaccine is free, the paperwork involved may be a disincentive for physicians to participate.

—the numbers of children who, by benefit of this program, become FULLY immunized. The goal of all our immunization efforts is to achieve 95% of infants being completely vaccinated by age two years. A VFC-participating physician must report the number of *vaccines* administered, not the number of *children* brought to full immunization. An infant must receive fifteen shots over four to five visits to be fully protected against polio, diphtheria, measles, and other vaccine-preventable diseases.

—the burden on health departments to receive, warehouse, properly refrigerate, distribute and inventory thousands of doses of vaccine. We feel public health resources can be put to better use.

Just because vaccine is available, does not mean that parents will bring children to the clinic, that children will be properly immunized by their care provider, or that state officials will have accurate immunization data to improve immunization strategies.

In response to the measles epidemic, the Centers for Disease Control took aggressive measures to hold each state accountable to determining its immunization needs and strategies. The CDC wrote *Standards for Pediatric Immunization Practice* which became a guide and blueprint for assuring higher immunization rates. Limitations in public health infrastructure were identified, and each state produced an "Immunization Action Plan" which identified objectives, processes, partners and time lines to improving the number of infants fully immunized.

In New Jersey, we have specifically focused available "Immunization Action Plan" funds to build a system which will provide for immunization assessment, referral and on-site vaccine administration for all children enrolled in WIC and AFDC programs. We have already established successful strategies by co-locating immunization and WIC services in AFDC offices to offer children and families "one stop shopping." These now exist in seven sites and two more will be added this summer. To address the critical need of measuring the impact of this state's immunization efforts, we are establishing a state-based electronic immunization information system. This system will facilitate a recall and reminder system for the parent and the private physician by which we can identify those children who need subsequent shots. We will be piloting this prototype electronic tracking system in one urban community this summer, which will link the immunization histories of patients attending WIC, AFDC, hospital pediatric clinics, FQHCs and several private physician offices.

There are, therefore, important immunization program needs, other than the bulk purchase and distribution of vaccine, which may be short-changed because of the redirection of money and effort to the VFC program. There is a need to sustain and increase funding of state Immunization Action Plans through 317 grant program funds. The 317 program allows each state the flexibility to design and implement an immunization program based upon its own unique sociodemographics and immunization needs. It facilitates our ability to identify and bring into partnership many important public and private players who will have a stake at living in communities with little threat of outbreaks from vaccine-preventable diseases.

Immunizing children is not a vaccine supply problem. If the latter were true, this country would not have 95% of all children appropriately immunized by kindergarten. This rate is a testament to the "gatekeeper" approach of requiring shots before school entry that demonstrates that full vaccination is attainable. This high percentage of fully vaccinated younger children is being seen in those states now requiring immunization for preschool and daycare entry and receipt of federal support in programs such as WIC and AFDC. Immunizing children is about outreach, access, recall, reporting and surveillance, as well as providing incentives and penalties. In summary, to sustain high rates of infant immunization, we must put functioning systems into place.

The national purchase of vaccine and the development of state distribution systems will not in and of itself assure high and sustainable rates of immunization. It will create another inefficient, government-run system. We have the opportunity, experience and vision to do better for our children.

Mr. BILIRAKIS. Thank you so much.

Mr. Goldberg.

STATEMENT OF ROBERT M. GOLDBERG

Mr. GOLDBERG. Thank you, Mr. Chairman.

Can you hear me?

Mr. BILIRAKIS. We can hear you.

Mr. GOLDBERG. My name is Robert Goldberg, and I am a senior research fellow at the Gordon Public Policy Center at Brandeis University, and I have been looking at this VFC Program for a long time, probably too long for my taste or for my family's taste. I developed the first analysis looking at the relationship of the costs as a barrier to immunization and early on identified some of the problems of the warehouse system.

What I want to do today is just restate some of the basic facts about the relationship between cost and immunization because up

until this time we have had a lot of rhetoric, and I think—I mean, not here in this room, present company excluded, of course, but just generally over the last couple of years. I mean, everybody wants to get kids immunized, and we know vaccines are cost effective.

But let's take a look at some of the facts. At age 5 or at school age, at least 90 percent of America's kids, even America's poorest are immunized. While Dr. Satcher said that sometimes it means one shot, in most States it means the full series of immunizations.

Now, at age 2, before age 5, over 90 percent of America's children in day care settings, including America's poorest, once again, are fully immunized when compliance is required, and we also hear from Dr. Satcher and others that when benefits such as WIC or AFDC are tied to proof of immunization, vaccination rates climb.

Finally, we also know that a large share of the children who are not fully immunized are poor children who see doctors 8 to 16 times by the age 2 and have access to free vaccine.

So the targeted question is, why are those parents who are not required to immunize their children not doing so?

Let me take a little step back into history to sort of explain why. I am sure you are going to hear, you have heard it this morning, and you will hear it from some other people on the panel that physicians referring kids out of the medical home into public clinics causes low immunization rates. Now, Groucho Marx once said, who do you believe, me or your eyes? To me, I have not come across any hard evidence to that effect.

On the contrary, supporters of the VFC invoke the measles epidemic of 1989 as an example of what happens when you refer kids out of the medical home. In fact, the Children's Defense Fund blamed high vaccine prices setting off what they termed, and I love this phrase, the lethal chain of events that led to the epidemic and death. The idea was, high vaccine prices took the kids out of the medical homes, they never showed up in the clinics, they got the measles and died.

Well, the body of evidence about the measles epidemic, which was conducted by NVAC and conducted CDC leads to an entirely different conclusion.

First, NVAC found that although immunization levels are 90 percent at the time of enrollment in school in the measles epidemic areas, they are reported to be as low as 50 percent among 2-year-olds in some innercity populations, the same district, different age group, some kids are getting immunized, some not. The difference isn't vaccine because the vaccine is free, it is the age.

Now, after that there were some other studies done that everyone has referred to here as well. Let me just quote the Baltimore study which was done in the wake of the NVAC study which showed that low immunization coverage levels observed in Baltimore—and, again, the bulk of the immunization problem is in the innercities—exists despite the presence of a large network of primary health care facilities to which these children have access, and despite the availability of health insurance, sufficient preventive health visits during the first 2 years of life and free vaccine.

So what has happened is that the States have gotten the message, and here is what some of the States have done. By 1991—

remember the measles epidemic was in 1989—the measles cases dropped off by 65 percent, and today only several hundred measles cases are reported. Now that success was achieved by spending $600 million less on vaccines than we are spending today.

Mississippi, which Dr. Thompson testified a couple of weeks ago said cost is not a issue, we have raised our rate to 90 percent.

Dr. Orenstein of the CDC has said Georgia has been able to double immunization rates without additional vaccine distribution. The CDC's own compliance experiences, and when Dr. Satchel says they have no way of evaluating, they do, Congressmen and Mr. Chairman, it is called a randomized control trial. You test one subject and leave the other one alone. They found that when you give people a 3-month WIC supply, their immunization rates go up by 60 percent.

You have heard of the State of Maryland study.

The State of Michigan is beginning to withhold 5 percent of school aid to local school districts that do not have 90 percent or above immunization rates, and I don't know if you have a copy of this, but they have reduced immunization in noncompliant districts by 100 percent, and they have here at the bottom free immunizations are available at local health departments and clinics across the State. They are raising immunization rates in these school districts using non-VFC dollars.

Now I am going to wind up here because I know the time is running short. Everyone is afraid we are getting the kids immunized. My daughter told me to tell you that she, in fact, is fully immunized despite my absent-mindedness. I just want to make sure that we make policy on the facts.

I think the strongest objection to the claim that was mentioned in the last couple of years that somehow eliminating VFC is like abandoning our children. The issue is, how do we immunize our kids. The way to do it, I believe, is let the States put the money into tracking primary health care services, carrot and sticks, and getting the job done, I believe, should be the only means by which we measure our ability to help our kids.

[The prepared statement of Robert M. Goldberg follows:]

PREPARED STATEMENT OF ROBERT M. GOLDBERG, PH.D., GORDON PUBLIC POLICY CENTER, BRANDEIS UNIVERSITY

Mr. Chairman, thank you for the opportunity to testify about the VFC program.

My name is Robert M. Goldberg and I am a Senior Research Fellow at the Gordon Public Policy at Brandeis University. I have been engaged in a study of the implementation of the Vaccines For Children program since it was introduced in March 1991, developing the first analysis of the relationship of vaccine cost to immunization rates and early on identifying the potential problems of the VFC warehousing system. I am here today because I believe a restatement of some of the key factors influencing immunization rates merit discussion at this point in the program's existence. More generally, I am concerned that since 1993 we have created and fought over the VFC program using little more than rhetoric. It's time to examine VFC purpose in terms of the facts.

Everyone in this room shares the primary policy objective of getting children immunized on time.

A national immunization policy is necessary. But that policy should be based on an analytical evaluation of the facts, which in case of developing an approach to increase immunization rates, are quite clear.

1. At age 5 or at school age 90 percent of America's children—including America's poorest—are fully immunized.

2. At age 2 or before age 5, over 90 percent of America's children in day care settings-including America's poorest—are fully immunized when such compliance is required.

3. When benefits such as WIC or AFDC are tied to proof of immunization, vaccination rates climb.

4. A large share of children who are not fully immunized are poor children who see doctors 8-16 times by age two and have access to free vaccine.

The question is: why are those parents who are not required to immunize their children, not doing so? What appears to be missing are three factors essential to improving immunization rates: parental initiative, physician participation, and a system of carrots and sticks that link obtaining benefits to immunization completion.

Mr. Chairman, allow me to elaborate briefly why we know that the absence of these factors—not vaccine cost—are the principal barriers to better immunization rates.

1. There is no hard evidence that physician referrals to public health clinics leads to low immunization rates. Supporters of VFC often invoke the 1989 measles epidemic in which low-income, inner city children were largely affected. The Children's Defense Fund blamed high vaccine prices as setting off what they termed the "lethal chain of events" that lead to the epidemic and death.[1] From this perspective, high vaccine prices led to doctors to refer parents to public health clinics. In turn, these parents failed to show up or were turned away from crowded public health clinics. This supposedly led to a decline in immunization rates which of course led to the measles epidemic.

The body of evidence collected on the measles situation leads to a different conclusion. First, a study conducted by the National Vaccine Advisory Committee (NVAC) found that "...although immunization levels are 97 to 98 percent at the time of enrollment in school, they are reported to be as low as 50% among 2 year olds in some inner city populations."[2] That is, older children in the same setting, facing the same circumstances were immunized, yet their younger counterparts were not.

Both 5 and 2 year olds had the same access to free vaccine or health care. The study found that "...only two states reported inadequate vaccine supplies in the public sector for routine immunization of preschoolers, despite the prevalent belief that this was a major problem."[3] One of those states, it turned out, was Washington which buys vaccine for all of its children.

The NVAC white paper concludes that the primary source of the measles epidemic was the failure to link immunization compliance to receipt of other services. The paper reports that "although inner-city preschool children are often described as hard to reach, many of these children are in regular contact with public assistance programs that typically see enrolled families every month....The failure to adequately vaccinate many children currently enrolled in public assistance programs suggests that many of the potential benefits gained by recent expansion in Medicaid eligibility to a much larger group of poor and near-poor preschoolers may not be realized unless steps are taken to assure that immunization is an integral part of program activities."[4]

Second, follow up studies on immunization patterns in Chicago, Philadelphia, Los Angeles and Baltimore reaffirmed the findings of the NVAC white paper. For example, the Baltimore study—which has been ongoing for two years has found that:

> "The low immunization coverage levels observed in Baltimore exist despite the presence of a large network of primary health care facilities to which these children have access and despite the availability of health insurance, (via Medicaid), sufficient preventive health visits during the first 2 years of life and free vaccine..."[5]

In probing further, it also became apparent that physician referrals to public clinics because of high vaccine prices played no role in creating missed immunization opportunities. On the contrary, the Baltimore study also found that a combination

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[1] Joseph Tiang-Yau Liu, Sara Rosenbaum, *Medicaid and Childhood Immunizations: A National Study*. The Children's Defense Fund, Washington, DC, January 1992.

[2] National Vaccine Advisory Committee, "The Measles Epidemic: The Problems, Barriers and Recommendation." Journal of the American Medical Association, Vol. 266, No 11, September 18, 1991, page 1548.

[3] ibid.

[4] National Vaccine Advisory Committee, "The Measles Epidemic: The Problems, Barriers and Recommendation." *Journal of the American Medical Association,* Vol. 266, No 11, September 18, 1991, page 1550.

[5] Bernard Guyer, MD, MPH; Nancy Hughart, RN, MPH, et. al., "Immunization Coverage and Its Relationship to Preventive Health Care Visits Among Inner-City Children in Baltimore." *Pediatrics*, Vol. 94, No. 1., July, 1994, page 57.

of parental delay in seeking preventive care and provider practices at sick and well visits...“serve to defer and delay achievement of age-appropriate immunization.”[6]

Based on the measles white paper and other studies, state and local government, a well as managed care organizations, have begun to increase parental responsibility and physician participation through a combination of more education, better tracking and a carrot and stick approach to increase immunization compliance. In essence, they are trying to duplicate the factors that get school age and day care children fully immunized.

Importantly, these policies are raising immunizations without having to buy additional vaccine.

- By 1991, measles cases dropped off by 65 percent and by 1993, only several hundred measles cases were reported. The key to success was education, better tracking and holding doctors and parents more accountable for getting children immunized against measles.
- Mississippi, “a state with one of the lowest per capita incomes in the nation, and one with limited public resources to address the prevention of disease, has achieved one of the highest immunization levels for its two year old children of any state.” According to Dr. F.E. Thompson, the state's health officer, “...we have not found the availability of vaccine, or its cost, to be a significant barrier...The real barriers are...our failure to remind parents of needed doses and our missed opportunities to immunize children we are already seeing.”[7] By setting up a tracking and reminder system in its public clinics, many public health districts were able to raise; completion levels of all two year olds to 90% without doing anything about the cost of vaccine.[8]
- Georgia has been able to double immunization rates among its poor families without additional vaccine distribution. Indeed, as Dr. Orenstein acknowledged in testimony last year, many clinics in Georgia have seen...“without...a major increase in funding, increased immunization levels among their clinic attendees from less than 40 percent...to almost 80 percent.”[9]
- The CDC conducted its own compliance experiments. It gave localities the opportunity to offer parents who could prove that children were up-to-date on their shots, a three month supply of WIC coupons as opposed to a one-month supply. These demonstrations in Dallas and Chicago increased immunization rates among the target population by 60 percent.
- The state of Maryland started a program three years ago that reduced AFDC grants by $25 a month for every preschooler who wasn't up to date on well-baby visits. According to Grace Clark, the program director for this experiment, “the information from our health department is that immunizations are up.” Other states, including Missouri, Michigan and Virginia are adopting similar requirements.
- The state of Michigan began withholding 5 percent of state school aid to local school districts that do not have 90 percent or above immunization rates. The number of non-compliant districts dropped by 100 percent in one year.

As you deliberate about VFC some states will say that the program is important. What they mean is that they are using the pot of money VFC provides. My analysis suggests that states are using VFC to free up resource for the sort of activities I have just described. The question is, would it not be more reasonable just to give states the money to take these actions in the first place? It is my opinion that federal support for fact-based solutions that work will insure that we are not needlessly diverting resources from other important child health issues.

If we base policy on the facts, not on rhetoric we can raise immunizations and free up money for compelling public needs. I take strong exception to the claim that eliminating VFC is somehow equivalent to abandoning our children and that throwing away precious resources in the form of a vaccine entitlement is the ultimate measure of how much we care. The issue is: How do we accomplish our mission to immunize our children accomplished in a time of limited resources? The way to do it is to let the states put the money into tracking, outreach, primary health care services and carrots and sticks. And getting the job done—not whether there is a

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[6] ibid. page 56-57.

[7] Statement of F.E. Thompson, Jr., M.D., M.P.H., State Health Officer, Mississippi State Department of Health Before the Committee on Finance of the United States Senate, May 4, 1995, page 4.

[8] ibid. page 5.

[9] Testimony of Dr. Walter Orenstein, Director, National Immunization Program, Centers for Disease Control and Prevention. US Senate Subcommittee of the Committee of Appropriations, Washington, DC, Wednesday May 18, 1994, page 21.

federal children's vaccine entitlement—should be the only means by which we measure our ability to help our children.

Thank you.

Mr. BILIRAKIS. Thank you so much, Dr. Goldberg.

Dr. Smith.

STATEMENT OF DAVID R. SMITH

Mr. SMITH. Thank you, chairman and distinguished members.

I would like to just quickly cover a couple of areas. The first is barriers, and the second is what we can actually do here today.

First of all, I am a pediatrician. I am the Commissioner of Health for the State of Texas, have been in that position almost actually going on my fourth year. I sit on the National Vaccine Advisory Committee also with Dr. Douglas, and have practiced and given immunizations from mainline in Philadelphia, from West Philadelphia to Southern Dallas where I worked at Parkland Hospital, to the Rio Grande Valley where this Congress and the National Health Service Corps had the wisdom to send me as a Joel Fleishman look alike to South Texas for my National Health Service Corps obligation. My southern exposure, quite frankly, was the best experience I ever had.

Let me talk a little bit about public health, changing times and what is going on in Texas. First of all, let's put in the perspective of the issue. We spend as a Nation less than 1 percent of our dollars on public health. That is why we are here today. This is far less than what we spend on the sickness care system. By the way, in Texas that is $47 per Texan I get in State, Federal and local money for public health, immunization is in there, by the way, $4,000 for the sickness care system, and $27,000 per inmate, just to put this all in perspective just for a second.

These are changing times. We have the biblical diseases in my State. I still have plague, TB, leprosy and rabies. I wish I had immunizations for all those problems. I wish I had immunizations for AIDS, violence and substance abuse. One would argue that maybe we would get a little further in all of this.

I also agree with some of my colleagues here, it wouldn't be the only way to fix the problem. We would have to have a system to deliver it, to track it, and to make sure that we put the pieces together.

Unfortunately what we have done here today is split the pieces. It gets back to Dr. Satcher's point, this is not just about access to the vaccine and the cost, which in my State is an issue. I have almost 2 million uninsured children. I have almost 9 percent of the birth cohort. In other words, the number of babies born each year. In my State, cost is an issue.

As I said this morning, if cost were not a factor, it must be the only market I know of where that is not the case. If cost is not an issue, I most certainly would be driving a Mercedes right now instead of a pick-up truck. I think the same is true here.

We looked at the Dallas study in 1989 and 1990 and actually noticed a 700 percent increase of migration from private practices to the public sector, and I was overwhelmed. We actually did turn people away in Dallas and Dallas County, and it led to an outbreak.

Leading cause, cost, not the only one, missed opportunities, all the issues you have heard today. But put it all together, this is not an either/or situation. We are making it that, it is not.

The other issue, when you start shifting kids from the private sector to the public sector, is actually not the one just cited. It is the fact that kids, yes, they will get their immunization. What about their vision, their hearing, what about screening for anemia, lead determination? That does get lost, and there are studies to show that when you disassociate well-child health, you do get immunized, and we have seen it in some of our clinics, you often will not find the other child health issues which can lead to absenteeism in school which is not something we want to see.

In Texas right now, we have taken this program. Our rates were deplorable, 30 percent of our 2-year-olds fully immunized in the 1989 series. We actually do have data and I am going to share it with you. At Texas A&M, they did learn how to count, and they were able to go out and do a household survey, a very accurate form, randomized in the State of Texas. We have elevated our immunization levels for 2-year-olds from 30 percent to 60 percent. Price is one of the issues and, again, it is not the only one. We have tied together programs with WIC, now with AFDC. We have gotten private industry in partners.

We now have over 1,900, close to 2,000 private physicians in the VFC Program, 1,700 public providers. We have distributed 5.1 million doses of immunization in this program, and we anticipate to do more. We would also like to see where the private sector could actually do some more of the distributions so that we don't have to buildup any more of our capacity and infrastructure. It is working. That randomized trial showed in Texas that our rates are up.

We have also gotten into the private sector in marketing. We have Aetna. We have 15 Fortune 500 companies in Texas in this partnership. That is what we should be talking about here today, not just how we can split the program of price, cost, and what we are doing in those other areas which are barriers.

The biggest barrier we are facing here today is uncertainty. As a State health official now going in the 4th year, that is always bad enough, my job in many ways is uncertain because the average State health officer's tenure is about 23 months, I think, and I got Medicaid 1½ years ago and that probably put me in a more vulnerable situation, but the reality is that if we change the rules and we keep changing for our public and private docs who now deliver 33 percent of all of our immunizations, where they previously did 23 percent, where is the trust? Are they going to go back and say, we can't trust anyone. Are we going to change the rules so that the changes we have made to make this system work will no longer work and kids will be without immunizations? I think that is a high possibility.

Very quickly five recommendations that I think we ought to work together, all of us, to try to bring together the issues of uncertainty, cost and those other barriers that Dr. Satcher talked about.

First of all, we do need to make sure there is a private market. I am worried about R&D for a lot of reasons. I want fewer shots for kids with more antigens in them. Let's get that data. On the NVAC, we did push further to make sure that that information is

going to come forth, and it will be presented, and I think it is good that this committee is getting involved, but let's see what it really costs. Let's take a look at R&D, but not necessarily the cost——

Mr. BILIRAKIS. Would you please summarize.

Mr. SMITH. I will, sir.

Let's take a look at another issue I know you want to tackle, insurance reform. Let's preserve private market by getting insurers both in and out of ERISA to cover first dollar immunizations. Do you want to preserve private markets, let's take a look at that.

Children's health, deplorable, 2 million Texas kids without children's health coverage. That is an issue. I can preserve private market. Let's link with WIC and AFDC. Let's invest in tracking because in our State, like yours, we track lottery tickets better than we do kids' immunization status. That is deplorable.

And let's also invest in marketing. We sell every day Nike's and McDonald's and hotel rooms. When did you see on a Super Bowl Sunday, the most expensive air time, one of our immunization advertisements. It is the most expensive air time. Proof will be in the pudding, the day that happens is the day we are serious about marketing. If we can't fix measles, folks, what can we fix, both in Washington and in Austin.

Finally, I just want to remind all of you the most poorly immunized group in this room are adults. I won't ask each of you, but think about your own status in pneumococcal, Hepatitis B, tetanus and influenza. Has your doctor talked to you about it?

Thank you.

[The prepared statement of David R. Smith follows:]

PREPARED STATEMENT OF DAVID R. SMITH, M.D., COMMISSIONER, TEXAS DEPARTMENT OF HEALTH

Chairman Bilirakis, Chairman Waxman, distinguished subcommittee members, my name is David Smith. I am the Texas Commissioner of Health and head of the Texas Department of Health. I am also representing the Association of State and Territorial Health Officers.

I appreciate the opportunity to talk with you about a topic that is a number one health priority in Texas: immunization.

In my tenure as Commissioner of Health I have looked for every way possible to increase the rate of immunizations in Texas. Immunizing children is one of the most cost effective health initiatives around. It is our goal in public health to immunize all children against preventable diseases. We cannot continue to look at measles, mumps and whooping cough as normal childhood diseases which every child goes through. These illnesses are serious, even deadly, and we have no excuse for not eliminating them in this country.

The Vaccines for Children Program (VFC) is one important element of our effort to wipe out vaccine-preventable diseases in Texas. In public health we are often challenged with piecing together a variety of programs and strategies to reach a goal. The VFC program contributes the following pieces in the effort to immunize our children: 1) it covers children that do not have insurance; 2) it creates public-private partnerships; and 3) it allows states to purchase more vaccines at a lower price.

Increasing Immunization Rates by Reaching More Children

The VFC program is critical in that it targets those uninsured children and those whose insurance does not cover vaccines. In Texas, only about 20 percent of the children have health insurance which includes the cost of vaccines. With the VFC program an eligible child can be taken to a regular family doctor and receive all the vaccines necessary, even if the insurance does not cover them. Therefore, this program not only helps to increase immunization rates, it also helps establish a medical home for the child.

It is my belief that every child in this country should be immunized, and this right should be an inalienable right and not a privilege. A child should be immunized regardless of ability to pay.

The Public-Private Partnership

The obligation we have to our children does not lie in the public sector alone; nor does it lie in the private sector alone. We must have a delivery infrastructure that encourages both public health clinics and the private physicians to participate. We need to remove any barriers which discourage private physicians' full participation in our efforts to immunize.

The VFC program is a vehicle which encourages public and private cooperation. We have worked hard in Texas to recruit private physicians to work with us in the laudable national goal of a 90 percent immunization rate of two-year olds by 1996.

Vaccine is supplied at no cost to all providers enrolled in the Texas Vaccines for Children program. To date, VFC vaccines have been delivered to over 1,900 physicians and to 1,700 organizations throughout Texas. The combined effort of public and private sectors represents an unprecedented approach to implementation of a prevention program and should be used as a model for other efforts.

If we were to dismantle the VFC program after all these relationships have been established we could jeopardize our relationship with the private sector. Many private physicians will view the short life of the VFC program as just another public sector mess that has cost them time and effort.

We don't need a system where private physicians refer children to public health clinics for immunization. We cannot continue sending people on a scavenger hunt for health.

Federal Optional Use Contract

The VFC program allows us to purchase vaccines at the federal contract price. The contract price allows us to purchase twice as many vaccines as we would otherwise. That is a good use of public funds.

If the VFC program is eliminated, Texas stands to lose a minimum of $26 million, the amount we will receive in calendar year 1995. We also would be faced with the costs incurred in treating diseases that could have been prevented with vaccines.

The VFC program offers a long-term strategy for increasing immunization rates. It establishes a system of care that incorporates vaccines and other preventive measures in health care. VFC brings private doctors into the system where public clinics may not exist, a common occurrence in Texas.

On behalf of all children, I urge you to continue this crucial program.

Mr. BILIRAKIS. Thank you so much, doctor.

Dr. Cooper.

STATEMENT OF LOUIS Z. COOPER

Mr. COOPER. Thank you very much, Mr. Chairman. It is privilege to speak on behalf of the 50,000 members of the American Academy of Pediatrics and the family physicians who truly are the backbones of medical care for 60 million children.

What I would like to do is talk about some results in a program that is 8 months old. If time permits, make a few comments because I am as concerned about the frightening comments made by the previous panel with regard to potential impacts on R&D as they are.

It is remarkable, New York is now the third largest State. What you just heard in terms of positive impacts of Vaccines For Children Program in the second largest State, Texas, a State that no one has any trouble distinguishing from New York, the results are remarkably similar.

We have gotten to where we are in this country in terms of our successes with vaccine because of the long tradition of public-private partnerships of vaccines and immunization and childhood immunization being remarkably bipartisan. For me one of the biggest downsides of this struggle that we have been going through for the last 2 years is the divisiveness that has been associated with at-

tempts to expand immunization to America's kids. It is about time that we brought that back together because this is either an issue that we do together or we don't do at all.

Everyone who has spoken from your committee, Mr. Bilirakis, has talked about the value of a medical home, and there is no question that access to a medical home, seeing that every child has his own physician, is at the heart of what immunizations are all about, and the success of a program.

Unfortunately, since this debate began several years ago, there are another over 2 million uninsured children in the United States. The Academy has supported the Vaccines For Children Program because it is a multifaceted program. Clearly cost is not the only barrier, but 60 percent of our membership has said that cost is an important barrier. That is true also for Dr. Conrad's State of Oklahoma.

The Vaccines For Children Program does support professional and public education that is much needed, outreach, tracking, we are building a registry in New York, something every member of this committee has said it supports.

Now let's talk about what has happened in 8 months. Not only has this program been overevaluated for the last 8 months, but also people have been using it in States like New York. What has happened is this, prior to Vaccines For Children Program we increasingly were losing our children from private doctor's offices into increasingly overloaded clinics. We were losing all of those other things that go with the medical home that Dr. Smith mentioned, the history, the physical examinations, the lead screening, the hemoglobin, the nutrition counselling, the counselling to do the injury prevention, to take the poisons out from under the sink, and so forth.

Since the Vaccines For Children Program has been implemented in a very difficult State, New York, a number of things have happened, and these are the data, 2,800 private doctors have enrolled, 475 institutional providers have enrolled, 2.8 million doses of vaccine have been distributed. What have been the responses from the pediatricians, 58 percent have said they have increased the number of Medicaid children they would see because of this program—we are doing what we have tried to do, get them back to their doctors—89 percent have said the VFC Program is good for children, and 87 percent have said that getting the vaccine through the distribution system that is still being worked out and refined but it has been quite reasonable and relatively convenient.

Furthermore, in terms of impact, of the 37 counties surveyed in New York, there has been a 30 percent drop in the visits to public clinics for immunization and we have made the shift to get kids back to where they get comprehensive care, not just a grab them and stab them approach.

Now New York's largest industry is health services, teaching and research. It is extremely fragile and its future is very problematic related to such issues as managed care, managed competition and the potential blocking of Medicaid. One of the things that is working is the Vaccines For Children Program. So I would urge you to allow it to mature, track it, keep it accountable, and all that goes

with it, but already it has proven its effectiveness in New York State.

For example, we now will move into the varicella vaccine. We couldn't do that under our cost containment except that now there will be funding for it. Hepatitis B has been a failure over the last 15 years. We have improved our Hepatitis B programs because of the Vaccines For Children Program.

Mr. BILIRAKIS. Could I ask you to summarize, Dr. Cooper?

Mr. COOPER. Sure.

VFC won't cure our problems in the delivery of child health in this country, no question about it, but from our experience as pediatricians across the country, it has been a valuable tool. It needs some fixing. We need to deal with the concerns expressed by the previous panel, but we believe if we come together in a dialog of this kind that we can sort out how to deal with R&D and, in the meantime, how we can make sure we get vaccine to the kids who need it. That has been our experience in New York and across the country.

[The prepared statement of Louis Z. Cooper follows:]

PREPARED STATEMENT OF DR. LOUIS Z. COOPER, DIRECTOR OF PEDIATRICS, ST. LUKE'S-ROOSEVELT HOSPITAL CENTER ON BEHALF OF THE AMERICAN ACADEMY OF PEDIATRICS

Mr. Chairman, members of the Committee, I am Dr. Louis Z. Cooper, Director of Pediatrics at St. Luke's-Roosevelt Hospital Center and Professor of Pediatrics at Columbia University in New York City, today representing the American Academy of Pediatrics. As one who has spent the majority of his professional life in the area of immunizations, from the perspective of a researcher, a practitioner, a parent and a policy maker, I share in our country's tremendous scientific progress, as well as this nation's responsibility to its youngest citizens in providing these benefits.

While the Academy looks forward to serious discussions with this Committee on how the needs of children and pregnant women can best be addressed under structural changes and budget reductions in the Medicaid program, today we are urging that the Vaccines for Children (VFC) program remain a federal program with basically the same structure. This is not to say that this program is perfect, nor should it continue in perpetuity. But in the overall scheme of things, with so many programs that impact upon children and their families in flux, the very least we can do is make sure our children are age-appropriately immunized, preferably in their medical home.

The VFC program provides an important remedy for obstacles to our nation's immunization initiative in three important areas: 1) it provides immunizations for the increasing number of children in working, middle-class families where dependent coverage is either not covered or has been dropped and allows them, as well as Medicaid recipients and Native Americans, to receive immunizations in a medical home; 2) it assures that all eligible children will receive the benefits of newly recommended vaccines for school entry, thus strengthening the immunity levels of the community; and 3) it gives states the option to purchase additional vaccines to cover those underinsured children who have typical insurance policies which do not include immunizations.

My testimony today will address these important provisions from the perspective of what the VFC program does for families, for communities and for states, all of which at interrelated. Although the VFC program is only 8-months-old, it is fast becoming an integral part of this nation's goal of protecting its youngest citizens from the ravages of vaccine-preventable diseases. It must be viewed within the context of all other public and private health initiatives—each contributing an important element.

FAMILIES

It was President Dwight D. Eisenhower who pledged, after the polio vaccine was licensed, that all children would be vaccinated, regardless of their ability to pay. This president, noted for his military prowess, knew the value of investing resources to protect children in particular and society as a whole. Implicit in this analogy is

an effective organization of the "troops." The past successes of our immunization programs exemplify the best cooperative efforts among federal, state and local governments and medicine's private sector.

As difficult as budgetary choices are, we must not shortchange our children. Simply put, when immunization rates decline, the incidence of diseases increases. Success cannot breed complacency.

The VFC program was initiated at the beginning of the health care reform debate to establish prevention as an early priority and protection of children as an essential element. It was simply a place holder until all children and adolescents had financial access to comprehensive health care, including immunizations. During the last year alone, 2.5 million more children lost private health insurance. These are the children of working, middle-class families and these are the families that depend on this program.

The VFC program is not a new entitlement. All children are entitled to be immunized at public expense (a combination of both federal and state dollars) in public clinics. Hence the issue at hand really is not whether all children will continue to be entitled to free vaccines but where they will have to go to get them. The VFC program simply facilitates the important symbiotic relationship and shared responsibility of both the public and private sectors in assuring all children are fully immunized. It allows families to stay in their medical home and receive immunizations as part of their ongoing, comprehensive care.

The essentials of an adequate medical home include: 1) geographic and financial accessibility; 2) continuity of care; 3) coordination through identification of needs and linkage of the family to services needed by the child; and 4) community awareness of child health problems and resources within the community. It is within the context of this medical home that we can work toward timely immunizations and eliminate missed opportunities. Why should immunizations become a two-step process where a family goes one place for well-child care and another for immunizations? Physician offices are open at night and on week-ends to accommodate working families; clinics are not. For many families, time off from work can be a very real barrier. While there are no studies that document the impact of delayed immunizations, why should we risk it?

The income level of families is irrelevant to this debate. It is the level of disposable income that is at issue when immunizations are needed. A variety of circumstances, such as household expenses or illness of other family members, weigh heavily on young parents. Under these common circumstances, disease prevention can become a much lower priority than the needs of day-to-day existence. Meanwhile, the unprotected child is at risk of acquiring a serious illness and/or infecting others in the community whose immune system may be compromised for a variety of reasons.

COMMUNITIES

As someone who has treated children with these diseases over the course of my career, the VFC provision that assures all eligible children will receive the benefits of recommended vaccines for school entry is a long overdue correction to our rational program. Before VFC, children who depended on the public sector for vaccines had to wait their turn as the dollars needed to purchase these vaccines were phased in over time. Simply put, we put at risk the most vulnerable in our society for lack of a few dollars. VFC puts fairness and humanity back in the system.

Accountability for vaccine purchases under this program are achievable at the community level. Speaking for my colleagues in the private sector, we applaud the commitment of this Congress in giving a high priority to administrative simplicity. We have participated in pilot studies with the CDC in looking for better ways to both order and track vaccine usage under this program.

STATES

A very important provision in the VFC program allows states to go even further, at their own expense, to cover underinsured children—children whose families have insurance but that insurance doesn't include immunizations. In essence, these working families with young children, who have the least insurance coverage and the least disposable income, are paying taxes that help subsidize public clinics and families with no dependent insurance coverage.

Twenty-one states and one U.S. territory have moved to rectify this problem and elected to become universal purchase states. These states have purchased additional quantities of vaccines at the federal contract price to cover these families. Other states, including my own of New York, have not attained universal status, but have

elected to purchase; additional vaccines for these purposes. Without the provisions in the VFC program, other states would be prohibited from this opportunity.

States with universal purchase status include: Alaska, Colorado, Connecticut, Delaware, Hawaii, Idaho, Illinois, Maine, Massachusetts, Nevada, New Hampshire, New Mexico, North Carolina, North Dakota, Rhode Island, South Carolina, South Dakota, Texas, Vermont, Washington and Wyoming. Puerto Rico also has universal purchase of vaccines.

Let's give these families a break! The Vaccines for Children program serves to promote parental responsibility, not hinder or fragment care for children. Its important provisions must be protected under any type of Medicaid restructuring. We cannot leave children's immunizations to chance.

Mr. GREENWOOD [presiding]. Thank you, Dr. Cooper.

Mr. Weill.

STATEMENT OF JAMES WEILL

Mr. WEILL. Thank you, Mr. Greenwood.

One of the central goals of the Children's Defense Fund is to encourage preventive investment in children before they get sick or drop out of school or get into trouble and that is why we are so positive about the VFC program. It is rare that a program can save human lives, improve the Nation's health and save public money.

VFC's success in doing all of this is because it attacks directly one of the primary causes of the underimmunization of American children, the cost of vaccines. As others who are proponents of this program have said today, there are numerous causes of underimmunization of America's children, not just cost. And since posters have been big today, I wanted to show you Children's Defense Fund and Chase Manhattan Bank have just launched a campaign in New York City and other cities aimed at parents to get parents to take their kids in to be immunized. There are multiple causes and we have to deal with all of those causes.

But the high cost of vaccines certainly plays a substantial role in providers not immunizing children even when children are in the doctors' officers. This, in fact, is what the missed opportunities that have been talked about all day are.

There are certainly irresponsible parents in this country who avoid getting their children immunized. But to suggest that one-third of America's parents, since one-third of 2-year-olds don't have a full set of immunizations, to suggest that one-third of America's parents are irresponsible misses the point and it is absurd. Rather, the issue is costs and missed opportunities which are linked together.

Because of costs, private providers' offices, children's existing medical homes too often refer children before VFC to overwhelmed public clinics for immunization. The GAO testimony that vaccine cost is not a barrier but that there is a real problem of missed opportunities during children's regular contacts with their health care providers is thus internally contradictory. These missed opportunities are happening and doctors and parents are foregoing opportunities. But the studies show, and the studies are attached to our testimony, that the opportunities are being missed precisely because of the increased vaccine costs that families can't afford.

Moreover, cost is likely to be a factor of substantially growing, not shrinking, importance in the years ahead. Cost is going to grow as a barrier because total vaccine cost to each family likely will rise as new vaccines come onto the market and cost is going to grow

as a barrier because more and more children are likely to be uninsured in the years ahead.

For the last 15 years, each year an additional 1 percent of America's children have lost private, employer-based health insurance. That trend is continuing. By the end of this decade, in the absence of significant health reform, fewer than half of the Nation's children will have private health insurance.

On the public side, the weakening of Medicaid is also going to cause cost of vaccines to grow as an immunization barrier. Reversing the Medicaid eligibility expansions for children of recent years would be a mistake and a block grant would be a bigger mistake yet, adding millions of children, mostly from working families, to the ranks of the uninsured.

So while it is important that children not bear the brunt of any Medicaid cutbacks, in fact we all know we are going to see Medicaid squeezed even if it is not slashed in the years ahead and children's underinsured is going to rise for that reason as well. VFC is thus a crucial bulwark against what promises to be a growing problem of uninsured families for whom cost is a barrier.

Let me also say that if VFC is part of a Medicaid block grant or made into a discretionary program or combined with some other discretionary program, I do fear for the future health of America's children The green light never went on but I assure you I will keep this within five minuets.

Mr. GREENWOOD. You are quite right. Therefore, you have something between unlimited time and no time.

Mr. WEILL. I will try to use both.

As we all know, we are entering an era of budget cutting that will be very tough on discretionary programs. If the committee looks at the funding history of some of the 1981 health block grants, including the preventive health block grant, and looks as well at the cuts in programs that are proposed in the House and Senate budget budgets for programs like the maternal and child health block grant, huge cuts, this does not suggest that the answer to the immunization problem in this country is a block grant or a discretionary program. These programs are going to shrink dramatically in the years ahead.

Moreover, the competing fiscal and political claims on State officials tell us that we can't have confidence in what the States will do on their own. Shortly before VFC, the Children's Defense Fund conducted a study of how State Medicaid programs had coped with the skyrocketing vaccine costs of the 1980's. States were not bulk purchasing vaccines for Medicaid in many instances because the manufacturers had lobbied successfully at the State level to forestall exactly that. And several States were reimbursing doctors for immunization services at a rate less than the cost of vaccines alone with no administration fee. We can be sure that there were tens of thousands of missed opportunities when States were responsible for doctors losing money every time they vaccinated a child.

To finish up, throughout the 1980's, as vaccine costs rose, efforts flagged in many, not all but in many States and that is why, as immunization rates rose throughout the world in the 1980's, they fell in the U.S. throughout the 1980's and early 1990's. That, in fact, is why dozens of children died unnecessarily in this country

in 1991 and 1992 and I firmly believe that if we forget this documented history, we will be condemned to repeat it.

[The prepared statement of James Weill follows:]

PREPARED STATEMENT OF JAMES WEILL, GENERAL COUNSEL, CHILDREN'S DEFENSE FUND

We appreciate the opportunity to testify in support of the Vaccines for Children program. The Children's Defense Fund is a national children's advocacy organization that exists to provide a strong and effective voice for all the children of America, who cannot vote, lobby, or speak for themselves. We pay particular attention to the needs of poor, minority and disabled children. One of our central goals is to encourage preventive investment in children before they get sick, drop out of school, suffer family breakdown, or get into trouble.

That is why we are so positive about the Vaccines for Children (VFC) program—a powerful early preventive investment. Despite some initial administrative difficulties, the VFC program has made an excellent start and is fulfilling its original promise of significantly reducing financial barriers to the timely immunization of children, especially infants and toddlers.

It is rare that a program can save human lives, improve the nation's health, and save public money. It would be a tragic mistake to cripple or destroy such a program—and thereby sacrifice children's lives and health and public money all at the same time. It is also rare that a health program has such strong support from federal officials and state officials and private providers. We see such support for VFC from the Department of Health and Human Services, from Republican and Democratic health officials in virtually every state, from the Association of State and Territorial Health Officials, from the American Academy of Pediatrics, and from the doctors who are signing up quickly by the thousands to participate in this program.

Overwhelmingly, the opinion of state health departments and private health care providers is that the Vaccines for Children program boosts immunization rates; is a key factor in maintaining the continuity of health care for children; forms a vital collaboration between the public and private health care sectors; reduces the burden on public health clinics, enabling them to serve more effectively their regular patients; allows the development of innovative state immunization programs that customize the provision of immunization services to specific populations; provides children in low and moderate income families with the same access to new vaccines as those in higher income families—an important public health consideration in the control and eradication of disease; and encourages the development of new and combination vaccines, leading to a simpler and more manageable immunization schedule. It is imperative that the Vaccines for Children program be retained in its current form so that states can continue to make progress toward the 90 percent immunization goal and the protection of all children from vaccine-preventable diseases.

The VFC program is successful, and it draws this support, because it attacks directly one of the primary causes of the underimmunization of American children—the cost of vaccines. Cost is, of course, not the only problem. But those who oppose VFC by saying there are other barriers to immunization miss the point and prove nothing. There are other barriers, and other initiatives as well as VFC are dealing with them. But we believe cost is the most important barrier, and nobody can dispute that it is one of the two or three most important barriers, and one that must be dealt with head-on.

There is abundant evidence in medical and public health studies that the high cost of vaccines was playing a role before VFC in parents not seeking immunizations, and in providers not immunizing children. As a result, private providers' offices—children's existing "medical homes"—too often referred children to overwhelmed public clinics for immunization. High vaccine purchase costs (and the resulting squeeze on reimbursement rates for administration of the vaccines) also prompted the referral of many Medicaid-enrolled children to public clinics for immunization. Unsurprisingly, it was precisely during the period that vaccine costs were skyrocketing (and young families' incomes dropping) that our nation's immunization problems worsened. There can be no question that vaccine costs play a significant role in the under-immunization of America's infants and toddlers. We have attached to our testimony a summary of studies that document the impact that the cost of vaccines has on immunizing children, and request that it be included in the record.

Cost is likely to be a factor of *growing, not shrinking* importance in the years ahead. It will grow because total vaccine costs to each family likely will grow as new vaccines come onto the market. Cost also will become an increasingly important factor because more and more children are likely to be uninsured in the years ahead.

For the last fifteen years, each year an additional 1 percent of American children have lost private employer-based health insurance. By the end of this decade, in the absence of significant health reform, fewer than half of the nation's children will have private health insurance. Just this year, an estimated 800,000 additional children will be uninsured—most of them from low and moderate income working families. In other words, cost of vaccines, in the absence of VFC, will grow inexorably as a problem for families so long as the problem of employers shedding dependent insurance (or reducing covered benefits) grows and remains unaddressed.

At the same time, the cost of vaccines is likely to grow even more important as an immunization barrier if Medicaid is weakened. The Medicaid program is much criticized in some quarters. But it has done an extraordinary job of insuring children and doing so at relatively modest cost (children are more than half of Medicaid recipients, but only represent one quarter of the expenditures). The Medicaid expansions of recent years, reaching mostly children from working poor and moderate income families, have offset much of the growth in uninsuredness on the private side. Now such growth is tapering off, and may be reversed in this Congress. Such a reversal would be a mistake—a block grant would be a bigger mistake yet. Shrinking Medicaid eligibility and services for children, or letting states do so through a block grant, would add millions of children to the roles of the uninsured and millions more to the ranks of those with bare-bones coverage, weakening children's health and our nation's productivity in the years ahead. As to VFC, even the most modest Medicaid changes will increase VFC's importance. In one form or another, to one degree or another, Medicaid will be squeezed. It is important that children not bear the brunt of this, and that the strengths of Medicaid's coverage of children be retained. But as Medicaid is squeezed, the number of uninsured children or children with providers who would refer out immunization work in the absence of VFC is likely to rise substantially. VFC is thus a crucial bulwark against what promises to be a *growing* problem of uninsured families and working families to whom cost is a barrier.

Repeal of the VFC program at this stage in its implementation thus would be a disaster for children, and dozens of state health officials have indicated their belief that state health initiatives and children's health would be damaged. The many children who now have access to free vaccines from their regular providers in their offices would be forced to choose between paying the high cost of vaccines or being referred for a special trip to a public clinic, regardless of whether the clinic was accessible, or whether the parents' work schedule permitted a timely second visit for shots. Children who are in a doctor's office or private clinic but are referred to a public clinic not only immediately miss an opportunity to be immunized, but face the potential additional barriers of an extra visit, inconvenient clinic hours, and long waiting times. The resulting attrition—fewer children immunized—is inevitable. By providing federally purchased vaccines to children in their own doctors' offices, the VFC program decreases the number of referrals, addressing the cost barrier in an efficient way that cannot be matched by the provision of free vaccines at public clinics alone.

Claims that the nation already has reached the goal of immunizing 90 percent of two-year-old children and therefore VFC is not needed are incorrect. While several specific immunization rates (rates of immunization for a single vaccine) are between 67 and 90 percent, the rate of immunization for the entire basic vaccine series (4 DTP, 3 polio and 1 MMR) is only 66 percent. It is this measure—immunization of a child against the full range of preventable disease—that public health experts use. Yet *one third* of our nation's two-year-old children (more than 1.3 million children) are inadequately protected against one or more common, preventable, potentially fatal or disabling diseases. While rates for individual vaccines went up in early 1993 compared to 1992, the picture is hardly rosy.

- First, the increases are *not* as described in a piece of paper circulated to some members of Congress by a pharmaceutical manufacturer saying incorrectly, "Source: CDC," and saying 1993 rates for two-year-olds for DTP and polio (3 doses) were 90 percent. This is not a Centers for Disease Control document. The actual numbers for 1993, were: for the recommended 4 doses of DTP, 72 percent; for polio, 79 percent; for MMR, 84 percent. (See attachment.)
- Second, the modest increases in 1993 compared to 1992 are encouraging, but are not nearly enough, and were bumps likely created by publicity on the importance of immunization engendered by the debate over this legislation and by attention to the recent epidemics. But the multi-year data and the 1993 data on children not fully immunized show the nation has a long-term systemic problem that needs a systemic solution.

States also would be severely affected by a repeal of the VFC program. Most states have invested time and dollars in developing the partnerships and infrastructure necessary to integrate the VFC program into their existing immunization programs. The VFC program has provided the first real opportunity for states to forge strong preventive care partnerships between the public and private health care sectors—partnerships that will improve the delivery of a range of health care services for children. All states have taken the opportunity provided by the VFC program to purchase additional vaccines at the federal contract price for some (in a few cases, all) children not eligible for federally-purchased vaccines. This option for additional state purchase is recognized by almost all states as a vital component of the VFC program.

In the absence of VFC, state Medicaid programs again would be required to pay the cost of vaccines for Medicaid-enrolled children. This would be particularly difficult in those states that already have improved administration fees for Medicaid vaccinations or otherwise re-allocated funds saved by VFC purchase for other purposes. Florida relied heavily on VFC to reduce its Medicaid budget (by $3.5 million), and reports that physicians across the state have embraced the VFC program. California has invested saved Medicaid funds in other childhood immunization services.

Finally, the assertion that the Vaccines for Children program will reduce the research and development of new vaccines is unfounded. The VFC program should stimulate vaccine manufacturers to invest in the development of new and combination vaccines, protecting children against additional diseases, requiring fewer vaccinations, and ultimately lowering treatment and immunization costs to society. Not only does the VFC legislation specify that research and development costs be considered as federal contract prices are negotiated, but it provides that new vaccines are not subject to a price cap. Through VFC, vaccine manufacturers therefore are provided a relatively quick, large and guaranteed market for new vaccines, at prices that will allow both adequate profit and research and development costs, immediately upon recommendation by the Advisory Committee on Immunization Practices. The program ensures that eligible children have access to *all* recommended vaccines, including new vaccines, as soon as they are added to the immunization schedule. This is a positive development for children, providers and manufacturers. In contrast, the Centers for Disease Control and Prevention's "Section 317" program, while another essential component of the nation's war on preventable disease, in many states provides insufficient quantities of some currently recommended vaccines, such as hepatitis B, does not provide other more expensive vaccines, such as the DTP-HIB combination, and does not guarantee the provision of new vaccines.

In short, the VFC program is already a crucial part of the nation's arsenal against deadly or disabling childhood diseases. At a time of concern about government costs, it saves many times its cost. At a time of concern about the public role, it represents an important public-private partnership to get Medicaid and uninsured children the care they need in their private doctors' offices. We urge the members of this Committee to support the VFC program and permit it to fully prove its tremendous worth in upcoming years.

Vaccination Levels Among Children Age 19-35 Months by Selected Vaccines—United States, 1992 to 1994

[Percent of children in that age group immunized]

Vaccine	1992	1993	First Quarter 1994	Second Quarter 1994
DTP/DT[1]				
3+ doses	83.0	88.2	87.0	90.2
4+ doses	59.0	72.1	67.2	70.4
Polio				
3+ doses	72.4	78.9	76.0	80.0
Hib[2]				
3+ doses	28.2	55.0	70.6	75.6
Measles	82.5	84.1	89.6	91.6
Hepatitis B				
3+ doses	-	16.3	25.5	29.4
4DTP/3 polio/1MMR[3]	55.3	67.1	66.0	67.7

Source: Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report 1994;43:705-718 and 1995;44:142-143,149-150,396-398

* The Vaccines for Children program did not start until the last quarter of 1994

[1] Diphtheria and tetanus toxoids and pertussis vaccine

[2] Haemophilus influenzae type b vaccine
[3] Four doses of DTP vaccine, three doses of poliovirus and one dose of measles-mumps-rubella vaccine.

SUMMARY OF SELECTED STUDIES DOCUMENTING THE ROLE OF VACCINE COST IN GROWING REFERRALS OF CHILDREN (SUCCESSFUL AND UNSUCCESSFUL) FOR IMMUNIZATION, AND IN THE UNDER-IMMUNIZATION OF CHILDREN

A 1993 survey of licensed pediatricians and family physicians in North Carolina showed that 93 percent of doctors referred children to public clinics for immunizations. Nearly all of the physicians (95 percent) cited parents' concerns over the cost of vaccines as a very important determinant in their decision to refer children to the health department.[1]

The number of children in Dallas referred to public clinics for immunization increased nearly *700 percent* between 1979 and 1988. The report stated, "A new influx of patients are using public sector immunizations, potentially creating additional financial stress for public health programs. In addition, this shift to the public sector may undermine the health departments' ability to provide new vaccines or protect greater numbers of children with immunization." In an earlier study, the authors found that 65 percent of children using public clinics for immunization did so because of high costs in private facilities.[2]

Milwaukee physicians reported immunizing uninsured patients in their offices less often than patients with insurance. Physicians estimated that approximately half of their uninsured patients decline private immunizations. The authors concluded that when children leave their physicians' offices without receiving immunization, an opportunity is lost. There is no assurance that families who decline immunizations in their physicians' offices for financial reasons will subsequently have their children immunized in a timely manner.[3]

After experiencing dramatic increases in the number of children seeking immunizations at public clinics, Orange County, California, health officials wrote, "Most private health insurance plans in the nation fail to provide coverage for preventive immunizations. As a result, many parents forego having their children immunized or use public clinics for immunization services. The public health system has been overloaded by the need to provide immunizations. As those in moderately difficult financial circumstances use the immunization services provided by the public sector, the traditionally underserved population in greatest need of immunization and at higher risk for vaccine-preventable diseases may be increasingly displaced. This factor may be exacerbating and feeding the U.S. measles epidemic. American families must be given the financial means to gain access to private physicians in their communities for childhood immunizations."[4]

In a northern California study, 61 percent of public immunization clinic patients had a family doctor or other medical home and would have preferred to have their children immunized by those providers. Most named cost as the main barrier to immunization at their usual well-child care sources.[5]

Medicaid and lack of health insurance were significantly associated with undervaccination in a medical chart review conducted in primary care offices in Rochester, NY. This review showed not only that missed immunization opportunities occurred frequently and contributed significantly to the undervaccination of preschool age children, but that the impact of missed opportunities was twice as great for children having Medicaid or no health insurance as for children covered by private insurance.[6]

When a random sample of members of the American Academy of Pediatrics was surveyed a majority (55.2%) of respondents reported referral of some or all of their patients to other providers for immunizations because of cost to the patient.[7]

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[1] Bordley W.C., Freed G.L., Garrett J., *et al*, "Factors Responsible for Immunizations Referrals to Health Departments in North Carolina," *Pediatrics*, 1994; 94:376-380.

[2] Schulte J.M., Bown G.R., Zetzman M.R., *et al*, "Changing Immunization Referral Patterns Among Pediatricians and Family Practice Physicians, Dallas County, Texas, 1988." *Pediatrics*, 1991; 87:204-207.

[3] Arnold P.J., and Schlenker T.L., "The Impact of Health Care Financing on Childhood Immunization Practices." *American Journal of Diseases of Children*, 1992; 146:728-732.

[4] Wagner G.A., Gellert G.A., Ehling L.R., "Insurance Coverage for Preventive Immunizations in Childhood." *New England Journal of Medicine, 1992*; 326:768-769.

[5] Lieu T.A., Smith M.D., Newacheck P.W., *et al*, "Health Insurance and Preventive Care Sources of Children at Public Immunization Clinics." *Pediatrics*, 1994; 93:373-378.

[6] Szilagyi P.G., Rodewald L.E., Humiston S.G., *et al*, "Missed Opportunities for Childhood Vaccinations in Office Practices and the Effect on Vaccination Status." *Pediatrics*, 1993; 91:1-7.

[7] Ruch-Ross H.S., O'Connor K.G., "Immunization Referral Practices of Pediatricians in the United States". *Pediatrics*, 1994; 94:508-513.

Half of the physicians responding to a survey in New York state referred some or all of their patients elsewhere for vaccinations. Most of the referrals were to a local health department clinic and respondents identified financial hardship as a "very important" reason for referral. In addition, more than half of the responding physicians indicated that some or all of the cost of childhood vaccination should be underwritten by the government.[8]

[8] "Physician Vaccination Referral Practices and Vaccines for Children—New York, 1994", *MMWR*, 1995; 44:3-6.

DANNY DEVITO HAD HIS.

Danny DeVito, 6 months

Every child under the age of two needs vaccinations to prevent childhood diseases. All it takes is five visits to the doctor and there's no telling how far your child will go. Give them five. Help them thrive. To find out how to get free vaccinations, call **1-800-325-CHILD.**

CHILD VACCINATION PROGRAM

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Mr. GREENWOOD. Thank you very much. I would like to address a question or two to Dr. Smith. You wanted to make the point, and did in your testimony, about price still being a barrier. I think you made a comment to the effect that if price wasn't a barrier in this market, it would be the only market in which it wasn't a factor.

What did you say was the rate of complete immunizations for children 2-years-old and under in your State?

Mr. SMITH. Currently it is about 57 percent, up from 30 percent when we did a study in 1989.

Mr. GREENWOOD. And what is it for your school-age kids?

Mr. SMITH. School-age children, I think we are somewhere around 96 percent.

Mr. GREENWOOD. Fifty-seven versus 96.

Mr. SMITH. That is correct.

Mr. GREENWOOD. Now, it doesn't cost any more to immunize a 1-year-old than it does a 5-year-old, right? I mean, those 5-year-olds, those school-age kids aren't immunized because it is less expensive to immunize them when they become 3, 4 or 5; is that right?

Mr. SMITH. The point that Dr. Satcher—and I actually disagree with Mr. Goldberg, in Texas, you do not have to have a full complete series which would be the best scientific way to be immunized in Texas so the cost, if you show up and need to get immunized for school—and, by the way, that burden is placed on the public sector in Texas. We are the ones that run the weekend, afternoon, school-based clinics to do what should have been done for the previous 5 years to all kids, rich, poor alike.

The reality is, though, that it does cost less because they do not get all of the different doses. They may not get the full series of polio, they may not get all four—in fact, they do not get all four EDTP. You just need to be up to date at that time and in Texas, since we are 9 percent of all the kids born, that's a lot of kids right there, so the answer to your question is, no, it is less expensive to do it at five.

And of course, the other side of the equation is that at two is when we are seeing the diseases and earlier and in Dallas alone, the cost of the immunization outbreak, in just hospital costs for 2,500 cases and 12 deaths, was $3.6 million. Not lost time from work, school, anything else.

Houston's outbreak, which followed, $5.2 million. Corpus Christi, $2.8 million, Star County $2.6 million. Just hospital costs.

So, again, we have to factor those things in too and one of the reasons why you see a diminution of cases after an outbreak is that kids get immunized by the wild virus that passes, some of which is asymptomatic. Not all kids get the rash and the fever.

Mr. GREENWOOD. What I am trying to get at here is the fundamental difference. Dr. Cooper lamented partisanship in this issue. I don't think it is a partisan issue. Republicans tend to be very fearful about big government, multi-billion dollar programs. We focus on individual responsibility and see what we can do to make individuals do things rather than focusing on what big governments can do, and they think exactly the opposite.

But did I hear you say, Dr. Smith, in your testimony or at least in your comments, that you did not have a problem with tying a

requirement to immunization to certain Federal programs, AFDC, food stamps, Medicaid; is that correct?

Mr. SMITH. Yes. We did not use policy changes but that is correct, sir. The answer to the question is you do all of the above. You try to deal with costs and it is a multiple choice question and the answer is, E, all of the above.

Mr. GREENWOOD. Okay.

Mr. SMITH. What we did is we moved WIC, we took away excuses all the way around. Our best success to date has actually been tying in with WIC. It was getting the vaccines and the nurses and a tracking system into that setting.

Mr. GREENWOOD. Let me ask you this question. We have seen instances in the country where we didn't do all of the above but where certain areas have tied the sticks to progress. They made gates for young kids into day care and so forth. We also have seen programs where they didn't do all of the above, but they tried to make free vaccine available. There are a handful, at least, of examples of that.

Which has shown the greatest increase in vaccination rates?

Mr. SMITH. Good question and I will answer that.

In the private sector in Texas, we have seen an increase from 22 percent of our immunizations, at that time 4.2 million doses going to the private sector, 22 percent of 4.2 million, where now we are seeing 33 percent of 5.1 million going to the private sector. In that market, cost was interestingly one of the most significant issues. Whereas, on the public sector side, we get into some of these other linkage opportunities, as I would describe them.

The overarching issue for us was bringing the private business community in to look at their own practices to partner and give us money for prime time advertising. And it all comes together, you're right. This is not an either/or, it should not be partisan.

Mr. GREENWOOD. I am not sure you are responding to my question. If you look at the instances where the primary modality was to make it a requirement to get WIC or other programs, and you compare it to programs where the primary modality eliminating cost as a barrier, what do you find?

Mr. SMITH. Correct.

Mr. GREENWOOD. Everything I have seen is that the gatekeeping approach, if you cannot afford to do all of it, is probably best. If you are trying to get the most rapid increase, it seems to me that all of the studies showed that gatekeeping gets you there first. If your goal is to improve it by 50 percent, you are going to get the first 30–35 percent out of gatekeeping and then whatever reducing the cost barrier gets you. It is the most expensive and the most bureaucratic way to get the smallest percentage. Isn't that fairly accurate?

Mr. SMITH. Not in a State with the number of uninsured that Texas has.

When we looked at the A&M study which looked at this issue, in the private sector, and our biggest gains were in two areas and they are almost the same, what we did in WIC is almost parallel to what we did in the private sector picking up more immunizations. This market in the private sector was cost driven, this one was tying the two together. So I can't disassociate. They both gave

me about the same bang for the buck which is well over 250,000 immunizations a piece.

Mr. GREENWOOD. Thank you very much.

Mr. Waxman?

Mr. WAXMAN. Thank you very much.

Dr. Smith, why don't I just continue on with you because you have experienced this program and you have run it in the State of Texas. We are all concerned with the low rates of immunization of 2-year-olds—not 5-year-olds because entering into school seems to make a big difference. Who are the people that are not immunized? Are they people who are getting benefits or are they immigrants who don't get any benefits, maybe a combination of them? Do you have anything to give us by way of information about these people?

Mr. SMITH. Yes, a little bit and I think some of it has been stated here today.

The answer to the question is, yes, they are both categories and lower middle class. In Texas, because 67 percent of our jobs are—actually we found a large problem in the small business market that wasn't providing coverage, particularly for kids. We are beginning to work with them so, interestingly, it was often the lower middle class, a wage-earner, as well as the symptoms clearly of our poor and also of immigrant, in migration across our borders and across our State borders. It is a problem for all of you because we have the largest migrant base. I mean Texas, and California is second. And our folks are all heading up to Maine, Wisconsin, Michigan and Washington right now. But the answer is, yes, to that question, all of the above.

Mr. WAXMAN. How big a problem is it of children who go to private doctors but don't have insurance for those private doctors who give the immunization?

Mr. SMITH. The study in Dallas showed a 700 percent increase in movement of the number of kids from private offices, many in north Dallas, to the public heath clinics in the period of 1989, 1990, 1991. The most significant cited reason by parents and pediatricians was cost. I do need to make a point here about the GAO study.

I was supposed to speak to these individuals twice, they canceled on me once, they never called back the second time after my name was given to them being on the NVAC and also on all of these other committees that I sit on including sharing the Interagency Work Group for CDC as well as running one of the largest programs. I find that interesting.

They also didn't talk to parents. If you want to talk about cost and barriers, then go interview some families in Lubbock and Spur, Texas, and figure out what they are. It is one of my big problems.

Mr. WAXMAN. Did GAO contact any of you at this table?

[No response.]

Mr. WAXMAN. So they didn't talk to Dr. Satcher, they didn't talk to the American Academy of Pediatrics, they didn't talk to at least two of you representing the people who run the program at the State level and then they came in with their report, saying that cost is not a factor particularly. That seems odd.

Well, I am concerned not about how this program in eight, 9 months is doing or not doing; I am concerned about what is going

to happen in the future because the world is going to be changed when this Republican budget is put into effect, if they succeed. One of the proposals is to take the Medicaid program and put it into a block grant for the States and tell the States: do all the things you do under Medicaid but you are not going to have to be accountable to us to show that you have done anything in particular and you have no obligation to provide any services to any individuals because they don't have any entitlement to services any longer.

If that happens, we have already seen the CDC funding for the immunization grant program reduced and we know that there is going to be even further large cuts in all discretionary spending. If we were to repeal the VFC program or simply add its funding to the Medicaid block grant, what impact will this have on the ability of doctors, State public health clinics and State health departments to ensure that the children in the State are properly immunized? Can States do this on their own without Federal Government involvement?

Dr. Smith, are you willing to try it?

Mr. SMITH. I have to actually reiterate something that Jim talked about just a second ago and that is what we are talking——

Mr. WAXMAN. Jim?

Mr. SMITH. Jim Weill with CDF.

I am concerned when I see what is happening to the preventive block and the MNCH block which were also in my Agency and if we are going to see those kinds of cuts, potentially one half, which do not duplicate what is happening in Medicaid, I am seriously concerned. This is about resources. It is about the dollars in VFC in my State, I took my $50 million that the State invests in immunization and is in fact paying for infrastructure, nurses, outreach, marketing and tracking system and we are tying our tracking system to our Medicaid data base and to our vital statistics so that we don't have more than one and it is linked together.

So in fact what would happen, I would have to shift dollars back out of those areas just to get back to where I was to buy 50 percent, 60 percent vaccine.

Mr. WAXMAN. Mr. Weill, you already mentioned this issue in your testimony. Dr. Cooper?

Mr. COOPER. It would be painful in New York State, very painful.

Mr. WAXMAN. Mr. Goldberg, have you looked at this issue? Have you thought about that?

Mr. GOLDBERG. The question again, Congressman? I'm sorry?

Mr. WAXMAN. If we see that the grant program for immunizations is decreased and we see the VFC program—childhood immunization program is thrown into a block grant of Medicaid, have you looked at that issue?

Mr. GOLDBERG. I tried to focus my research on the impact of the entitlement components of the VFC program. As I think I indicated in my testimony, the 317 components of the immunization program, I sort of took as a given. So whether they are a retrenchment overall of immunization funding or a lumping into it, I mean it remains to be seen. I happen to think that all things being equal, immunization should and probably would receive a priority but I think the 317 aspect has been a mainstay and probably should remain so.

Mr. WAXMAN. Dr. Gursky?

Ms. GURSKY. I believe the commitment to immunization from the State level will be strong. I concur that decreased funding will be a problem but clearly from everything that has been stated today, immunization is a major issue at the State level. I believe the State levels, by virtue of our immunization action plans, are capable of handling our own particular immunization needs and clearly even if it were not a concern for children and the health of children and the health of our communities, it has been very clearly brought out today that vaccinating children saves us money so immunization will be a priority.

Mr. WAXMAN. Everybody is for it and we want to make sure it continues. Mr. Weill I noted you wanted to respond to my question but I just want to follow up one question with Dr. Gursky.

If we ended up eliminating the purchasing of vaccines by the Federal Government in bulk and then distributing to the States or helping the States get it at a lower price, which seems to be part of what the drug companies would like as a way to give them extra inducements for research and development, you had to therefore negotiate on your own for vaccine purchases from the manufacturers, do you think you would be spending more for vaccines? Would that hurt your efforts when combined with the effect of the block grant that has these childhood vaccine funds thrown into it?

Ms. GURSKY. I believe we would go back to negotiating vaccine prices as we did previously and that we would use nonvaccine-directed funds for infrastructure efforts that would favorably affect our immunization outcomes.

Mr. WAXMAN. So you would have less nonvaccine funds if you were paying more for vaccines?

Ms. GURSKY. That is correct, but I think that the remainder of those funds given to our discretion would work on infrastructure and tracking systems which would answer our immunization problems.

Mr. WAXMAN. Mr. Weill?

Mr. WEILL. I think your question made my point. The block grant really is a triple whammy; it is less Federal money, children aren't good at competing politically at the State level within a block grant for funds, so they would lose more, and then the prices would skyrocket where there was no constraint and then the manufacturers would not sell in bulk to the States the way they do the Federal Government. So you would have these three forces going on. States would be able to buy a quarter or a third of the vaccine they are currently buying. It would be a disaster.

Mr. WAXMAN. Well, my time is long expired but I would just make one rhetorical statement. And that is you are suggesting that children's needs aren't always given a high priority but everybody says they are for immunization, everybody says they are for children. I guess the reality is even though we are all for it because it all makes sense, the funds don't always flow in that direction.

Mr. WEILL. That's right.

Mr. KLUG. Mr. Bryant?

Mr. BRYANT. Well, thank you, Mr. Chairman. I am going to have to go downstairs and vote again. This markup has kept me running in and out of here and I apologize.

I would first like to say, if I might be parochial a moment, I first thank all the witnesses for being here. Dr. Smith from Texas has to come in and out of town twice to get here and I appreciate him very much for making the effort and I apologize I wasn't here the whole time.

I would like to say it is curious to me that GAO didn't talk to anybody at this table but had time to go out to California and photograph the lobby of this hotel and blow these pictures up for us. I guess we are just overworking them.

I think Mr. Waxman made all of the points that I would have attempted to make in my questioning. The fact that we have gone from 30 to 60 percent in Texas since 1989 has got to reflect an enormous cost savings to us in the long run and the points made by Dr. Smith with regard to the workability of this program in a great big, very diverse State—a lot of folks forget we have 18 million people in Texas, we're as big as New York State, we have three enormous metropolitan areas right in the middle of it that are in the top seven in the country in population.

I think we need the program and I won't burden everybody with rhetorical questions. Thank you, Mr. Chairman.

Mr. KLUG. Gentlemen, thank you. This has been an awfully long day—and gentle lady, my apologies.

I guess we have one final question for you.

If we ultimately decide to shift to a block grant and figure out a way to carve out money specifically for an immunization program, if you had your choice, would you narrowly focus the money that the State could spend only on purchasing vaccines or would you like to have the flexibility to do other things?

Dr. Gursky?

Ms. GURSKY. I feel strongly that we need the flexibility because each State's needs are very different. I think you should hold us accountable State by State for raising our immunization levels but our States are different, our needs are different and we need the flexibility to be accountable to you.

Mr. KLUG. Mr. Goldberg?

Mr. GOLDBERG. I would agree with Dr. Gursky. And I would also make an additional point that many of the panelists here and many of the State health officials that I have spoken to talk about using VFC as a way of freeing up other funds to do things that are more important than reducing the cost of vaccines. That is sort of a Rube Goldberg way of doing it—he is not a relation of mine; I want to clear that up for the record.

Why not just give them the money directly to do what they want and, indeed, there are other advocate groups that are not at this table, including the Children's Health Fund that have suggested the primary comprehensive primary health care services apart—that kind of money should be focused and targeted rather than taking the money and just giving it the vaccine. So I think that in the context of the block grant, you get a pretty good bang for the buck.

Mr. KLUG. Dr. Smith, one way only or flexibility?

Mr. SMITH. I think the real question is how much.

Mr. KLUG. I'm asking the questions.

Mr. SMITH. I know, but I flew in from Texas and I would have to answer and the answer is how much. That really is the fun-

damental issue, can you cover the need? Still, the question remains which is actually Dr. Douglas's question which is still how much because can we then begin to deal somehow with this differential needed for R&D. So really the answer to the question is, how much.

Mr. KLUG. Well, assuming it is the same money it is today just for the sake of argument. Would you want flexibility or only purchasing?

Mr. SMITH. You mean assuming current levels of 317 plus current levels of VFC all rolled up together?

Mr. KLUG. Yes.

Mr. SMITH. And including the ability to add new vaccines?

Mr. KLUG. The question is, do you want flexibility or do you only want us to——

Mr. SMITH. But it is the real world I live in; I have to worry about a constantly changing birth cohort and people moving in and out of my borders and people traveling to your State right now picking vegetables. It is not that simple.

Mr. KLUG. Dr. Cooper?

Mr. COOPER. Same answer as Dr. Smith. We need the flexibility, sorry. We need the ability to bring in new vaccines and as long as we can have the ability to bring in new vaccines, as long as States can purchase at a federally negotiated price rather than going one on one. I would say that I fear government as a single purchaser but if you think the government is a tough purchaser, wait until you have to deal with Aetna and Prudential who have no need whatsoever to be concerned about long-term R&D or any pharmaceutical company. So we have got a difficult balancing act that we have to deal with.

Mr. WEILL. If, as you indicated, it is the current level, I would put aside roughly the portion that is in VFC now for purchase and let the States use the rest flexibly for outreach, for tracking, for other purposes.

Mr. GREENWOOD. Again, thank you all very much for coming. I appreciate it.

Thank you, Mr. Waxman, for hanging tough as well.

Thank you.

[Whereupon, at 5:15 p.m., the hearing was adjourned, to reconvent at the call of the Chair.]

[Additional material submitted for the record follows:]

ASSOCIATION OF STATE AND TERRITORIAL HEALTH OFFICIALS,
WASHINGTON, D.C.
June 15, 1995

The Honorable MICHAEL BILIRAKIS,
Chairman, Subcommittee on Health and the Environment,
U.S. House of Representatives,
Washington, D.C. 20515

Dear CHAIRMAN BILIRAKIS: Thank you for allowing us the opportunity to provide written testimony on the subject of the Vaccines for Children program. The Association of State and Territorial Health Officials (ASTHO) represents the public health department in each state and U.S. territory. One of the unique and most positive aspects of the Vaccines for Children program is that states may innovate in their maximization of the program's benefits; therefore, state health officials have a unique perspective on the program's successes and future potential to impact our nation's childhood immunization rates. As your subcommittee is conducting an oversight hearing on the Vaccines for Children program, I hope I will be of service in describing states' experiences with this initiative.

While states understand that the Vaccines for Children (VFC) program has had some start-up problems, it is nevertheless a very valuable tool for many states and promises to be of ever greater value as implementation proceeds. I would like to describe some of the benefits provided to states by the VFC program:

Increasing Immunization Rates—First and foremost, VFC helps states come closer to reaching their 90 percent immunization goals. The state of Delaware estimates that the Vaccines for Children program will increase the state's immunization rates by 10-15 percent.[1] North Dakota states that "immunization levels in 1994 were approximately 68 percent. Immunization levels in 1995 are anticipated to increase to 85 percent with the 90 percent goal reached in 1996 as a result of the universal vaccination program."[2] The Oregon Department of Human Resources says that "there are thousands of children being immunized through VFC who would not be eligible for state-supplied vaccine any other way."[3]

As a nation, we have been successful in recently increasing our childhood immunization rates, yet we should not forget that millions of children are born each year in this country. Our immunization strategy should be long-term, not sporadic. VFC establishes a system for the long-term immunization of children, not only for existing vaccines, but for new ones such as chickenpox. While some antigen-specific data may appear to indicate that we are close to our 90 percent goal, when considering which children have had all their shots, the numbers are lower. (For example, some children may have had their DTP, some their polio, and some their MMR, but they are not necessarily all the same children.) There are two million children between 19 and 37 months of age who are not series-complete (4 doses of DTP, 3 polio and one MMR).[4] Moreover, this series does not consider vaccines that we normally administer to infants, including Hib and Hepatitis-B. In summary, our work is far from over.

Universal Purchase Option—Another benefit of the Vaccines for Children program is that states may supplement the federal purchase of vaccines with state purchases at the "federal contract rate." This allows states that wish to provide vaccine for all their children to do so by adding their vaccine orders to the federally negotiated contracts with vaccine manufacturers. As an example, Illinois estimates that without this option to purchase, its buying power would be reduced by at least 25 percent, or approximately 120,000 fewer doses of vaccine.[5] This arrangement also benefits vaccine manufacturers, which achieve market stability from the commitment of the federal and state government contracts. The importance of this aspect of the program to states cannot be overemphasized.

Strengthening the Public-Private Partnership—Vaccines for Children also takes a positive view of health care by strengthening the public-private partnership. The program provides free vaccines for eligible children to be given in the child's "medical home" which reinforces the importance of a primary care provider and strengthens the link to other medical services. Florida has stated that "physicians across (the state) have embraced the VFC program... VFC has increased the availability of culturally sensitive immunization services for historically hard-to-reach patients."[6] In many states, any remission of the VFC program would represent a serious breach of faith with the provider community. Oregon is another active participant in the program and believes the public-private link is critical. The Oregon Department of Human Resources is "actively recruiting and training private providers to initiate or increase immunization services. Without VFC, this public/private partnership would cease to exist. Even more devastating is the likelihood that this team approach would be forever destroyed. The private sector would never again trust the government to assist their efforts to improve immunization rates.[7]

Cost Savings for States—According to an informal ASTHO survey of state health departments conducted in March, many states are expecting that they will experience significant savings due to implementation of the Vaccines for Children program. The estimates of such savings range from approximately $200,000 per state to one state that anticipates about $12 million in savings. States are demonstrating creativity and innovation in redirecting savings anticipated from the program, including: bolstering of vaccine administration fees for physicians; financing for immunization of "underinsured" children (those whose insurance does not cover immunizations) in public and private settings; provision of new vaccines such as varicella,

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[1] *Excerpts From States' Responses on Impact of VFC/317,* ASTHO, 1995.
[2] Ibid.
[3] Ibid.
[4] *MMWR*, March 1995.
[5] *Excerpts From States Responses on Impact of VFC/317*, ASTHO, 1995.
[6] Ibid.
[7] Ibid.

and for other additional cohorts of specific vaccines such as Hepatitis B and measles, mumps and rubella (MMR); development and enhancement of state-wide immunization information tracking systems; vaccine purchase for children who are not VFC eligible; financing of new vaccines, such as varicella, for children in universal purchase rates; and supplemental funding for development of community-based Immunization Action Plans.[8]

In spite of the benefits to states described above, several issues have been raised about the usefulness of the program. The argument is occasionally made that the price of vaccines is not the true impediment to achieving high childhood immunization rates. While cost is only one of the several identified barriers to immunizing children fully, there is substantial research to indicate that cost is a factor requiring a remedy for many families. For example, a 1993 survey of licensed pediatricians and family physicians in North Carolina showed that 93 percent of doctors referred some children to public clinics for immunizations. Nearly all (95 percent) cited parents' concerns over the cost of vaccines as a very important determinant in their decision to refer children to the health department.[9] Clearly, cost is an issue which should be addressed if our effort to increase immunization rates are serious. Additional impediments including inadequate outreach, education and tracking, and insufficient clinic hours, are also being tackled at the state level, often with the help of VFC savings. We encourage Congress to support these efforts and to work with states and providers to address all barriers to full childhood immunization, including cost.

Finally, some questions have been asked about the method by which VFC vaccines are distributed, given that CDC was unable to sign distribution contracts with all the vaccine manufacturers. Of the 49 states participating in the Vaccines for Children program, 35 have public and private distribution systems in place; the remaining 14 states were left without a system of distributing to private providers when the planned national distribution system was cancelled just before the program's start date. However, these 14 states are in various stages of developing their own distribution system to private providers and plan to be fully operational later this year or sometime in 1996, at the latest.

Mr. Chairman, I appreciate having the opportunity to provide state health departments' views on this important program. While state health officials recognize that the Vaccines for Children program's implementation has encountered its share of challenges (not unlike many programs in their earliest stages), the program's current benefits and potential bode well for states and our nation's children. Moreover, ASTHO believes that the commitment has been made by the federal government to states, private providers and parents and should not be withdrawn, nor the program scaled back, especially at this critical implementation stage. Thank you for your interest in this important public health matter.

Sincerely,

CHRISTOPHER ATCHISON,
Director, Iowa Department of Public Health
President, Association of State and Territorial Health Officials

[8] *ASTHO Statement on Estimates From States on Anticipated Savings From the Vaccines for Children Program*, ASTHO, 1995.

[9] W.C. Bordley, G.L. Freed, J. Garrett, et al, "Factors Responsible for Immunization Referrals to Health Departments in North Carolina," *Pediatrics*, 1994.

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